VA & HUMAN TISSUE: IMPROVEMENTS NEEDED FOR VETERANS SAFETY

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VA & HUMAN TISSUE: IMPROVEMENTS NEEDED FOR VETERANS SAFETY

Wednesday, April 2, 2014

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:13 a.m., in Room 334, Cannon House Office Building, Hon. Mike Coffman [chairman of the subcommittee] presiding.

Present: Representatives Coffman, Lamborn, Roe, Huelskamp, Benishek, Walz.

OPENING STATEMENT OF CHAIRMAN MIKE COFFMAN

Mr. COFFMAN. Good morning. This hearing will come to order.

I want to welcome everyone to today's hearing titled VA & Human Tissue: Improvements Needed for Veterans Safety. This hearing focuses on VA's continuing problems with the tracking and management of biological implants which include skin grafts, bone grafts, heart valves, tendons, and other products that use human tissue.

In a previous hearing in January, this subcommittee examined continuing issues regarding prosthetic procurement, in particular VA's over-reliance on open market purchases that are potentially the most expensive procurement method and may pose the greatest risk to patient safety.

VA contends that waivers are necessary to accommodate clinician preference for products with which they are familiar. However, our investigation of this billion dollar industry shows that there may be ulterior motives.

In this regard, over 57 percent of biological implants are procured by VA as open market purchases, and we have found that several VA clinicians serve on the board of directors of at least one of the major suppliers to VA of biological implants on the open market.

VA's failures regarding biological implants go well beyond possible conflicts of interest in procurement practices. Our investigation reveals that the problems include VA's failure to adequately vet biological implant vendors to make sure that they are registered with the Food and Drug Administration and that they are utilizing best practices such as those established by the American Association of Tissue Banks.

Even more concerning is that VA lacks any ability to identify the sourcing of the material used in biological implants and track it

from donor to recipient. The lack of such a track and trace system poses very serious and unnecessary risks to patient safety.

Although it is very difficult to attribute adverse events to tissue product contamination, one recent example of a contaminated transplant shows the ramifications. According to a report in the Journal of the American Medical Association, the kidneys of an air force recruit from North Carolina who died from a rabies infection in July 2013 were transplanted into a Maryland veteran who later died from complications with rabies.

Illegal trafficking of human tissue jeopardizes the supply chain of biological implants. A 2012 report from the International Consortium of Investigative Journalists indicates that trafficking of human tissue crosses international boundaries.

One of the most egregious examples of such trafficking within the United States is the case of a dentist in Brooklyn who lost his license due to drug addiction and who then created a massive scheme to plunder tissue from funeral homes including from people who had died of cancer, HIV, and infectious diseases. He would pay undertakers, falsify required records, and then he would sell the tissue under the business name Biomedical Tissue Services.

Significantly at least one of the alleged customers is a current supplier to VA and has received repeated citations from the FDA for cross-contamination issues. Apparently VA took no action to address this major safety violation with that company even after receiving a biological implant from the vendor.

GAO and the VA's Office of the Inspector General have documented weak inventory controls that make it difficult if not impossible for VA to identify the patients and to whom they were implanted.

In its written statement, GAO found that VA uses informal tracking systems that are not standardized or shared across departments and that even when used are prone to error because they rely on manual data entry.

In its statement for a previous related hearing in January, GAO found that for some clinical specialties including gastroenterology, interventional radiology, and pulmonary, identifying information on implants was not tracked in any system.

Given the incomplete and inaccurate data regarding inventory control, serious doubts are raised about VA's ability to identify patients in the event of contamination or a product recall.

It is troubling to consider, but in an investigation in March of 2012, VA's Office of the Inspector General found expired products remaining on VA's inventory shelves. Fortunately, the FDA has developed a unique device identification system that if deployed by VA would facilitate reliable tracking and tracing of biological implants.

I urge VA to implement this system and to develop an automated inventory control system that is compatible with the unique identifiers. VA needs to make VHA the premier health care delivery system it aspires to be.

It should lead the Nation in the adoption of FDA's unique device identification system for all types of biological implants even before FDA's implementation deadlines.

The six million veterans served annually by VHA deserve the highest standards of patient care in the Nation.

With that, I recognize Ranking Member Walz for his opening statement.

OPENING STATEMENT OF HON. TIM WALZ

Mr. WALZ. Well, thank you, Mr. Chairman, and thank you for your continued care of our Nation's veterans and willingness to make sure we do our job of oversight.

But I would also like to thank Ranking Member Kirkpatrick for her work on this and for the opportunity to allow me to be here today.

We are here to talk about VA's surgical and biological human tissue implant purchases and the ability of VA to safely track these. I am looking forward to exploring the progress that VA is making in maintaining accountability of implants and what impediments, if any, stand in the way of VA instituting a system-wide policy to verify vendor VA registration.

Last year, nearly 60,000 tissue products were used at VA medical centers. Ensuring that these are safe and reliable needs the full attention of the VA and of this subcommittee. Tissue implants can provide amazing relief to the suffering of our veterans, but as with all these technological wonders, there are risks that the chairman mentioned.

In January, we held a hearing to investigate VA's procurement of surgical implants. There were a number of shortcomings noted by the GAO including a lack of an automated mechanism for tracking.

I look forward today to hearing about the progress VA is making in this effort and what further steps are required not only in the area of human tissue but in the larger area of surgical implants and prosthetics. Implementing a system-wide implant tracking system utilizing bar code technology for blood products are important steps to ensuring patient safety.

I note that the VA has established a working group to look into improving management of biological implants. I would like to hear today whether VA can move faster to develop a single comprehensive tracking inventory management system for all biological implants.

Finally, I look forward to hearing what system VA has in place so that implants can be tracked and appropriate action taken if the FDA issues a recall. In addition, I look forward to hearing how VA will ensure vendors are registered with the FDA.

Last week, we held a legislative hearing on a draft bill, Biological Implant Tracking and Veterans Safety Act of 2014, addressing some of the concerns of Congress and expanding the implant tracking requirements.

Unfortunately, VA was unable to testify on the draft at that time. I look forward to hearing your thoughts today.

Mr. Chairman, I want to thank you again for your work on oversight. And with that, I yield back.

Mr. COFFMAN. Thank you, Mr. Walz.

I ask that all Members waive their opening remarks as per this committee's customs.

With that, I invite the first panel to the witness table. On this panel, we will hear from Mr. Philip Matkovsky, assistant deputy under secretary for Health for Administrative Operations, Veterans Health Administration.

He is accompanied by Dr. William Gunnar, National Director of Surgery for the Veterans Health Administration, and Dr. Michael Icardi, National Director of Pathology and Laboratory Medicine Services for the Veterans Health Administration.

Please come to the table.

Mr. Matkovsky, your complete written statement will be made part of the hearing record and you are now recognized for five minutes.

STATEMENT OF PHILIP MATKOVSKY, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR ADMINISTRATIVE OPERATIONS, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY WILLIAM GUNNAR, NATIONAL DIRECTOR OF SURGERY, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; MICHAEL ICARDI, NATIONAL DIRECTOR OF PATHOLOGY AND LABORATORY MEDICINE SERVICES, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS

Mr. MATKOVSKY. Mr. Chairman, Ranking Member Walz, and Members of the committee, thank you for the opportunity to appear before you this morning to discuss the Department of Veterans Affairs' sourcing, procurement, tracking, and oversight of its biological implant purchases including implant tissue.

I am joined today by Dr. William Gunnar, national director of Surgery, and Dr. Michael Icardi, national director of Pathology and Laboratory Medicine Services.

Over the last eight to ten years, utilization of biological implants including implant tissue has grown significantly resulting in the doubling of dollar value of the biomaterials market since 2004.

However, the field of biological implants continues to rapidly evolve with new advancements in tissue fabrication, nomenclature standardization, and industry governance.

In procurement, VHA recently completed its transition of procurement duties from prosthetics purchasing agents. This transition resulted in the removal of warrants from staff who are not contracting officers and procurements above the micro purchase that are now performed by our contracting officers with warrants.

While Title 38, Section 8123 grants broad authorities to the secretary of VA for the procurement of prosthetics appliances, we have now integrated our prosthetics purchasing authority with FAR and VA acquisition regulation provisions.

In this integration, the 8123 is primarily employed as a statutory basis for a FAR part 6 justification. This is for other than full and open competition.

What this means in practice is that if a clinician who has been trained on a particular product has felt comfortable with that product, then they can be assured that a government procurement official will not restrict them from selecting and using a product with which they feel competent for their patients.

This application of our prosthetics authority enables clinicians to make choices based on their medical determination of what is best for our patients.

In complicated systems, it is always possible to improve our management and tracking controls. We have made significant progress often setting industry standards in tracking medications, blood products, and implants. However, we do acknowledge we can improve our tracking and inventory management of biological implants including tissue.

In 2013, the Food and Drug Administration published a final rule requiring most medical devices distributed in the U.S. carry a unique device identifier or UDI and that information concerning each covered device be submitted to the global unique identification database.

The rule does contain a staggered compliance date. With the advent of this new identifier, systems should be able to track a specific item and associate it with the manufacturer. This will improve adverse event tracking and will further enable greater automation and product recalls.

However, I do need to be clear. This rule does not yet apply to biological and tissue implants. VHA will be participating with the FDA this summer in the formulation of this policy and applying it to biologics and tissue implants.

With the more recent developments in the biological implants industry and in reaction to external audits and reviews as well as this committee's oversight, VHA has established a work team to identify improvements to our sourcing, management, and control of biologics.

This work team is expected to complete its review and recommendations in the third quarter of fiscal 2014. We will review their product and then begin the process of establishing a standard protocol across each of our medical centers.

Similarly we have charged a work team to develop a set of new national contracts for biological implants. This work team is in the phase of procurement that we call the development of requirements. The team is comprised of clinician leaders as well as logistics and prosthetics specialists.

We expect our procurement packages to establish stringent quality standards not available on previous federal supply schedule contracts.

My personal performance contract contains the expectation that this solicitation phase for this new procurement action will be initiated prior to the end of fiscal 2014.

In conclusion, our mission in VHA is the delivery of timely, quality, patient-centered care. Our systems must apply controls where appropriate to further this mission.

We acknowledge we must seek to find and implement improvements to our management, tracking, and control of biologics items. We are committed to making necessary changes to our policies, practices, and systems to improve.

We must, however, ensure our procurement system achieves and complies with all federal laws and regulations, but that it also achieves a balance. It must enable our physicians whom we trust

with the most critical decisions to apply clinical discretion when needed to provide veterans with individualized health care.

Mr. Chairman, this concludes my testimony. I appreciate this committee's continued interest in and care of the health and welfare of America's veterans. At this time, my colleagues and I are prepared to answer your questions, sir.

[THE PREPARED STATEMENT OF PHILIP MATKOVSKY APPEARS IN THE APPENDIX]

Mr. COFFMAN. And thank you for your testimony.

Dr. Matkovsky, there are at least ten VA doctors on the board of directors for the Musculoskeletal Transplant Foundation of which VA has purchased over $1 million in biological implants over the past 15 months.

Is this relationship a conflict of interest?

Mr. MATKOVSKY. Mr. Chairman, thank you for your question.

All of our employees are required to declare by our ethics policy any conflicts of interest. As a matter of fact, in each of our clinical committee meetings, they are required to announce any conflicts of interest.

We researched some of these assertions. We went back and identified each of the clinicians and we did not find in our review any involvement in the procurement decisions associated with the MTF organization.

I would add that the Musculoskeletal Transplant Foundation is a nonprofit organization which I do believe is an AATB accredited tissue bank.

Mr. COFFMAN. Thank you.

I think that the entity you just referred to did $4 billion of business last year.

The criminal conflict of interest statute in 18 United States Code, Section 208 prohibits a federal employee from participating personally and substantially in a particular official duty that will have a direct and predictable effect on the employee's own financial interest.

Do the VA clinicians who sit on the board of biological implant vendors violate this statute?

Mr. MATKOVSKY. I do not believe they did, sir. They are required by policy to notify their management of any conflict of interest, any boards they may sit on. And if they are involved in a procurement decision that may be associated with a firm with which they might be associated externally, they are to recuse themselves from that transaction.

We did not find an instance where they were involved in that procurement decision.

Mr. COFFMAN. Mr. Matkovsky, according to your memo dated May 23rd, 2012, surgical implants are required to be bought on the FSS or federal supply schedule unless a waiver is obtained from the director of the National Acquisition Center.

Is a waiver obtained from the director for every surgical implant purchased on the open market?

Mr. MATKOVSKY. In many cases, the biological implants that are acquired are below the micro purchase threshold. Since those are

not going to be affected by a procurement organization or contracting officer, many of those do not have a waiver.

I will point out that in, I believe it was fiscal 2013, there were 21 waivers. That may not sound like a large number, but that is a waiver for a contract that would be a local contract that would cover many purchases.

We have actually requested that our contracting officers increase their scrutiny to ensure that anything that we are acquiring that does not conform to the VAAR, this is the VAAR hierarchy, that we have waivers for that. We are able to monitor that now much better in the procurement organization.

Mr. COFFMAN. My understanding, it is something like 97 percent of the purchases are micro purchases?

Mr. MATKOVSKY. I think in the biologics area, it is about 95 percent.

Mr. COFFMAN. It just seems to me, I mean, that there is an intentional effort to negate the rule by virtue of doing the smaller purchases.

Mr. MATKOVSKY. Well, you know, with all due respect, sir, I do not know that that is necessarily the case. In many cases, these are acquired in time for a surgical procedure. So a surgeon may be going into a procedure and will acquire that item.

A dermal graft may be a micro purchase, but in some cases, some of our dermal grafts have to be stored at negative 43 degrees Fahrenheit and, you know, the storage requirement for that would negate us having it around for quite a while.

So you will acquire it in time for the procedure and we are not keeping a significant stock of these items. So you will see smaller purchase items.

Having said that, I want to be clear. We do want to have a clinically cleared national contract available for us that includes certification and accreditation and then promulgate that contract for broad use.

Mr. COFFMAN. Mr. Walz.

Mr. WALZ. Thank you, Mr. Chairman.

In your testimony, sir, you said VA is developing implant tracking in cardiology and surgery and wants a single comprehensive tracking system.

What is the time frame on getting to that single comprehensive tracking system?

Mr. MATKOVSKY. Some of that will depend, Congressman Walz, on our analysis. We have a group that is meeting face to face next week. We do expect the recommendations in the third quarter.

Some of what we are going to have to do is going to require an interface to VistA, CPRS. Those interfaces to VistA will have to be an IT funded requirement. As we went through our IT requirements exercise for fiscal year 2015, implant tracking and alerting was one of our higher priority items to get funded.

But there will be some requirement on IT funding to be able to deliver the completed system. I will tell you that as we looked across what we are doing in some of our networks today, there are commercial systems that are bar code enabled systems that would allow us to better track both in the OR setting and in the outpatient setting.

That may be possible. It may be possible for us to acquire that with medical resources which might expedite that portion of it. The connect to VistA, though, would require an IT fix.

Mr. WALZ. Well, I am probably not telling you anything new, but coming here with IT funding request is going to be met—I am not sure. I will let my colleagues use the words they will use on that, but this is a difficult one because of the roads we have been down.

So I ask you to make sure that we have evaluated that thoroughly because more requests for more IT when we still do not have seamless transition between DoD, that is a tough sell. I hear what you are saying, though.

Other than the part played by the National Center for Patient Safety, VA has taken a somewhat decentralized approach to tracking.

My question to you is, and I started to research this, I represent the district that has the Mayo Clinic, how would an organization like that do this as opposed to the VA, if you can give me your insights on how that works, if you know?

Mr. MATKOVSKY. I am going to defer to some of my colleagues here. And in response, we will answer two questions. I think one of them is our recall process and then the question might be, you know, our tracking in blood and the extension of the blood tracking that we do today, we have, frankly, been doing that for decades down to the patient level. And I will ask Dr. Icardi to weigh in.

We have a three-step process for recalls. The first question is, do we have this item in our inventory? Is it something we have acquired? And on a recall, the first action is to pull from inventory.

Then there is a clinical decision to determine whether or not there is clinical significance for a patient directly and then lastly the patient involvement and close out with the patient which may involve tracking. It may involve removal of an implant, for instance, a hip.

But let me ask Dr. Icardi to walk us through a little bit of what we have done in the blood bank since 2006.

Dr. ICARDI. Since 2006, we have had the VBECS system up which allows us to go through and track all of our blood products and combined with what the FDA and CDC does. That allows you to track a blood product from when it is initially collected all the way till its final disposition.

Mr. WALZ. That is how a large private sector would do the same way?

Dr. ICARDI. Yes.

Mr. WALZ. Best practice that way?

Dr. ICARDI. Yes.

Mr. WALZ. Okay. Okay. The next one I have, and this one I am still trying to wrap my mind around, in the GAO report, it states that there is a possibility that VA has utilized tissue implants from vendors that have not registered with the FDA.

My question is twofold again. How is that happening, how does it happen, and do you believe that it is happening outside the VA also? Is this a system-wide problem in health care delivery because this one seems pretty staggering to me that that would be allowed to happen? So, please.

Mr. MATKOVSKY. Quite frankly, I am not quite sure the nature of that finding. I think that the nature of that finding would be that in review of the recorded purchasing transactions that some of them, they would indicate that the record keeping might indicate that it is not an FDA. I do not have any indication to confirm that, quite frankly.

Do I think it is a broader issue across the health care industry, I cannot opine.

Mr. WALZ. So what you are saying is they may have been or they should have been registered, we just do not have the paperwork to prove that they were registered?

Mr. MATKOVSKY. No. I think it is just a matter of record keeping, ensuring that what we have in our national prosthetics patient database is the valid recording. And if it contains information that may be subject to human error, then there is some question as to whether or not that would be——

Mr. WALZ. Does it concern you that that might be the case?

Mr. MATKOVSKY. Well, I think we want to have a standard national contract that we know has clinical input into it, quite frankly. So, yes.

Mr. WALZ. Okay. With that, I yield back. Thank you, Mr. Chairman.

Mr. COFFMAN. Dr. Roe.

Dr. ROE. Thank you all for being here today.

And let me just go over a few things. And first of all, these biologics and as I have looked into this, and obviously they had been tremendous for patients. There is no question about that.

I think one of the concerns we had and certainly in my State of Tennessee is when we had an outbreak of some contaminated epidurals medication that caused some people to die. It was contaminated with a fungus and we were able to trace that right back to its source, stop that and not use that source.

The way I understand this from the GAO report and the part that I read is that when you buy, some of the vendors that you buy from have not been FDA approved; is that correct?

Mr. MATKOVSKY. I think that is in the report, I believe, yes, sir.

Dr. ROE. That is not what I asked. I said is it correct?

Mr. MATKOVSKY. I do not know that it is correct, sir.

Dr. ROE. Okay. So you do not know for sure that it is or is not. Okay.

Mr. MATKOVSKY. Correct.

Dr. ROE. Fair enough. And when these are placed, do you tell the patients that they are getting a biologic? Do they understand?

And let me explain where I am coming from. Because the patients expect us, the system to make sure what goes in them is safe, they expect us to have done our due diligence.

And if you look at tissue, allograph tissue, it can come from foreign sources and some of those sources, and I have done a little bit of research on that, one story from the Ukraine and they had bins of tissue that was contaminated.

And what patients do not understand is this has to be retrieved under certain conditions. And there have to be people who are excluded who have cancer, who have any infectious disease. Certainly the case that the chairman brought up with rabies obviously should

never have been. That is a different system, tracking system of organ transplantation as opposed to allograph transplantation.

But patients have that right and if that happened, if a patient was contaminated by, let's say, hepatitis C, hepatitis B, does the VA have a system that could track those patients down?

Mr. MATKOVSKY. We do. It is important to note as we——

Dr. ROE. You are saying to me now that even though some hospitals do not have a system that is tracking it, the VA could track that from its source of origin to that individual patient? You all have that system in place? That is good if you do.

Mr. MATKOVSKY. I will walk through the scenarios that we have that I can state definitively, Congressman Roe.

Since roughly 2008, there have been 13 recalls for biologics that have triggered a National Center for Patient Safety action within the VA. Six of those we had in our inventory.

I am going to ask Dr. Gunnar to walk us through a little bit about that recall process, but it is important to note that in six of those that we had, we had in one of our medical centers some inventory.

There is then a clinical determination as to whether or not we need to notify the patient, and I am going to ask Dr. Gunnar to elaborate on that. But in those recall instances, we have been able to track the inventory, facility, and then take clinical action.

Dr. ROE. Just a commentary before he does. I would absolutely think you ought to notify the patients. I mean, that is the most affected person. And I think out there now, if I am a patient that got a new anterior cruciate ligament and I found out later that the source was contaminated, I think it would at least be fair to tell that person so they could be tested.

And we have been down this road before with contaminated colonoscopes and other things. This is not new.

Mr. MATKOVSKY. In a couple of these cases, the recall itself was rescinded.

Dr. GUNNAR. I can assure you, Congressman Roe, that in those situations, we would—there is policy, VHA policy regarding disclosure of adverse events and National Center of Patient Safety would work with the program offices as well as the facilities and the providers to identify the individuals who received that implant and make sure that the correct clinical action occurs.

Dr. ROE. But what I am hearing from you all is is that there is a system to do that now, so——

Dr. GUNNAR. Correct. There is a system in place to do that now. What we do not have is that single button and I think that is what this other—what the bill supposes that we would have a bar coding system, that we would be able to go to one source and push the button and the list would come up. And, unfortunately, we do not have that source.

Dr. ROE. Okay. There is another issue that does not affect the VA, but the FDA, and that is, and this is a little bothersome, this is not anything to do with you all at all, but when they approve a tissue bank, sometimes they do not go back for years to ever examine that tissue bank.

And that is a little worrisome because the patients expect us and the surgeon who uses material that he or she is used to using—

I get that. I mean, we got our little toys we like to use. But we expect that that particular piece of tissue that we get is safe when we get it. I mean, we are assuming that the people who procure that for us have done the due diligence to make sure that when we do transplant that into a patient, that that patient is getting a safe graft.

And I guess the other thing I will ask, Dr. Gunnar, you, does the staff inform patients that they are getting an allograph? I know I always did, but it is not required, I do not think.

Dr. GUNNAR. It is actually by policy required in our time-out process. So the implant is actually—you have to—before the patients—the procedure even starts, you have to assure that the implant is there, that it is not——

Dr. ROE. No, no, that is not what I mean. I mean, does the patient know they are getting an allograph?

Dr. GUNNAR. Yes, in the informed consent process.

Dr. ROE. And I am sorry I ran over just a second here, but the other one is is how do you for expired tissue, and that is obviously very important, that the GAO found still sitting on the shelves, why did that happen?

Dr. GUNNAR. Well, I believe that was some time ago and Mr. Matkovsky can comment about how the inventory was managed following that. But what I can tell you is that there has now been the policy that ensures correct surgery and invasive procedures requires that there be a read back of the expiration date on any biologic that is going to be implanted.

Dr. ROE. Well, do you think any expired tissue has been implanted into anybody?

Dr. GUNNAR. I am sorry.

Dr. ROE. Tissue expired——

Dr. GUNNAR. Yes.

Dr. ROE [continuing]. Got to the operating room, got implanted into a patient, has that happened?

Dr. GUNNAR. To my knowledge, that has not happened, but I think there is a culture of safety that is developed in the VA that is associated with a national policy that would provide assurances that that would not occur.

Dr. ROE. Well, it could if that tissue was still sitting there on the shelf.

Anyway, I yield back.

Mr. MATKOVSKY. I would simply indicate, though, I mean, I think the discussion of the tracking and alerting mechanism, we do need that. We need a mechanism to better manage the inventory and facility. I would concur.

Mr. COFFMAN. Dr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman. Appreciate the chance to discuss this issue today.

First I want to turn to Mr. Matkovsky. The National Center for Patient Safety, that is internal to the VA; is that correct?

Mr. MATKOVSKY. That is correct, sir.

Dr. HUELSKAMP. And as I read and review the GAO report, they presume that all the recall notices and such coming out of that NCPS are sufficient and conclusive of what needs to be recalled. Is that your understanding?

Mr. MATKOVSKY. We believe so, yes, sir.

Dr. HUELSKAMP. How different is that from other systems that impact this particular industry and how is it different than what is in the industry? Again, this is only internal to the VA and the GAO assumes every recall that was necessary was identified by NCPS.

Mr. MATKOVSKY. I think NCPS is actually an aggressive organization inside. I think it has a very forward leaning stance. It works with programs. I think our scale is different than other entities in the private sector. But other than that, I think it functions in much the same way as a recall entity would in the private sector.

But it is a very strong coordinative entity that can trigger a recall either from an internal source or from an external source, works with the program office be it surgery or blood, pulls data where we can at the national level and then can issue a recall notice down to the facility and follow it through to its completion.

Dr. HUELSKAMP. Does this work together with the FDA?

Mr. MATKOVSKY. If the FDA issues a recall, yes, sir, it would. So it would trigger an FDA recall, would trigger a patient safety alert for us.

Dr. HUELSKAMP. When you do that with non-FDA vendors, how do you work with those if, again, they are not registered with the FDA and they are not approved by the FDA, but you are using their products?

Mr. MATKOVSKY. If there is a recall action, we would be notified and then we would initiate the recall action for that item. I am sorry. I am not sure I understand.

Dr. HUELSKAMP. I do not understand why you are working with non-FDA vendors. Could you describe why you are working with non-FDA vendors in this particular arena?

Mr. MATKOVSKY. I do not know that we are working with non-FDA vendors, sir.

Dr. HUELSKAMP. Didn't the GAO report identify that?

Mr. MATKOVSKY. I think they indicated that given record keeping issues that——

Dr. HUELSKAMP. You have no idea if you are working with non-FDA vendors; is that correct?

Mr. MATKOVSKY. I do not believe that is correct, sir.

Dr. HUELSKAMP. You said you do not have the paperwork to determine that you always work with FDA vendors.

Mr. MATKOVSKY. No. I think the GAO comment was that we could not assure given our record system that we work——

Dr. HUELSKAMP. And you are assuring me today you are not working with any non-FDA vendors?

Mr. MATKOVSKY. I can take that for the record and research.

Dr. HUELSKAMP. Yes or no?

Mr. MATKOVSKY. I will take it for the record, sir.

Dr. HUELSKAMP. So you cannot assure us today you are not working with non-FDA vendors? That is the GAO report. That is what they are saying. You do not have the paperwork to identify that? I am just trying to get the basis of that. So you are taking that system which you do not have the paperwork for, that is also the basis for which the GAO indicates you are following your own internal standards for a recall? Are there recalls that take place

elsewhere in this country that the NCPS did not feel proper to have a recall within——

Mr. MATKOVSKY. In many cases, we will have a recall that is not triggered by the FDA. Our own internal organization may trigger more recalls than would be triggered outside.

Dr. HUELSKAMP. My question is, is there a recall that elsewhere in this particular industry that the NCPS chose not to precipitate within the VA system?

Mr. MATKOVSKY. I do not know. I do not know of any.

Dr. HUELSKAMP. Could you provide any proof of that for later reference? I would appreciate knowing.

Mr. MATKOVSKY. I would also go back and I will research the data down to the granular data to look at every vendor we have purchased from.

Dr. HUELSKAMP. Okay. Well, I appreciate that because that is core from the GAO report because there is not the data there to answer the question to say, hey, yes, we are only working—is there a reason you would work with a non-FDA vendor?

Mr. MATKOVSKY. There is none, sir.

Dr. HUELSKAMP. There is none whatsoever?

Mr. MATKOVSKY. I think the other thing that is also getting lost in some of this, the GAO is performing an audit function against the data we can provide. It is a time limited audit. We are going off of data we can provide.

There is an accreditation function that occurs in each one of our facilities. Each of our facilities is a Joint Commission accredited entity that has its own processes reviewed by the——

Dr. HUELSKAMP. And I understand that, but you are using the VA's National Center for Patient Safety as the basis for making these decisions. That is all internal to the VA. My concern is an external source on that.

Lastly, you made some reference in your oral testimony, it is not in your written testimony, about personal performance contract. Could you describe that a little further?

Mr. MATKOVSKY. I will, sir. Following our hearing on January 15th, I went back and modified my performance contract and added in there that we would have a clinically cleared national biologics contract by the end of—sorry—the requirements set by the end of this fiscal year. So we would go into the solicitation process. So I have modified my performance contract to be personally accountable.

Dr. HUELSKAMP. Okay.

Mr. MATKOVSKY. I think it is important.

Dr. HUELSKAMP. You modify your own contract with the Federal Government?

Mr. MATKOVSKY. We all have a performance agreement, so I inserted into my performance agreement working with my boss at the time. She and I had a discussion when I came back from this hearing and I thought that I needed to ensure that I was personally accountable to make sure we did this.

Dr. HUELSKAMP. Can we receive a copy of that personal performance——

Mr. MATKOVSKY. Absolutely, sir.

Dr. HUELSKAMP. That is the first time I heard about that and the first time I have heard anybody say they altered their own personal performance contract. So did you get a bonus last year and that is——

Mr. MATKOVSKY. I think mine is still in deliberation, sir. I think it is a performance award and I think it is still in deliberation.

Dr. HUELSKAMP. Is it based on your old written contract or it is based on your new one? Do you——

Mr. MATKOVSKY. My new one will take effect for the period of fiscal 2014. At the conclusion of fiscal 2014, if I am unable to actually deliver a requirements package for biologics, it will affect my personal performance, yes.

Dr. HUELSKAMP. So you do not know if you got a bonus for fiscal year 2013 from six months ago?

Mr. MATKOVSKY. I do not, sir.

Dr. HUELSKAMP. When will they tell you as an employee?

Mr. MATKOVSKY. I do not know.

Dr. HUELSKAMP. Who makes that decision?

Mr. MATKOVSKY. I also do not know. I am not sure I want to.

Dr. HUELSKAMP. You have a contract. You do not know who makes the determination on the bonus?

Mr. MATKOVSKY. Things happen.

Dr. HUELSKAMP. Actually, they do not happen.

Mr. MATKOVSKY. Well——

Dr. HUELSKAMP. Sir, I have a hard time believing you do not know who is making a decision on whether you get a bonus or not.

Mr. MATKOVSKY. I believe the secretary makes the decision——

Dr. HUELSKAMP. Okay.

Mr. MATKOVSKY [continuing]. And reviews it.

Dr. HUELSKAMP. So the secretary makes the decision. He has waited six months and has not told you yet; is that correct?

Mr. MATKOVSKY. That is correct.

Dr. HUELSKAMP. Thank you. I yield back.

Mr. COFFMAN. Dr. Benishek.

Dr. BENISHEK. Thank you, Mr. Chairman.

I thank you all for being here this morning.

Dr. Gunnar, are you involved in the process of fixing this? I mean, Mr. Matkovsky has said how they do not quite have the plan yet or do not have an accurate method of tracking all this stuff right to the patient, I guess at the macro level really because I think in each hospital, they sort of track it.

But are you involved in that process? I mean, it looks like you are the director of Surgery for the VA. So I always like to have the doctor involved with, you know, a lot of this stuff. So I just want to know if you are involved in that.

Dr. GUNNAR. So I am involved in the surgical world and was instrumental in modifying the VistA surgery package back in 2011 to actually add implant information at the time in the OR. The VistA surgery package is not used for out of operating room procedures.

And the majority of biologics, to take it back to the subject of this hearing, are actually applied in the outpatient arena. I think for that reason, we have testified that conceptually we want to align

this with the blood bank concept of bar coding and being able to——

Dr. BENISHEK. So, Dr. Icardi, then would you have——

Dr. GUNNAR. In the world of biologics——

Dr. BENISHEK. You have not really been involved in that process?

Dr. GUNNAR. But I am involved.

Dr. BENISHEK. Yeah.

Dr. GUNNAR. Yes, absolutely.

Dr. BENISHEK. Well, it sounds like you said that you were involved in the stuff that went to the OR but not involved in the stuff that did not get to the OR, so is that correct? It is more like a blood banking issue and then the blood banking people are more in charge of that sort of thing then? Is that what you are saying?

Dr. GUNNAR. Congressman, this is, and I appreciate the question, this is the work group that is established will come to a decision in the third quarter of this year.

Dr. BENISHEK. Well, the point I am trying to get at, Dr. Gunnar, is that, you know, I get very uncomfortable. You know, I am a general surgeon, too, and I get uncomfortable when people who are not physicians are making decisions that affect patients. I think as physicians, our primary concern is for the patient, at least mine always was.

Now, you have that whole team working behind you when you are in the operating room and you want to be sure that they are all doing their job. And, you know, I understand that you cannot oversee that piece of material from the beginning to the end yourself. And I would like to see that physicians are at least in charge over the process or involved in the discussion, so——

Dr. GUNNAR. Dr. Icardi, to answer your question specifically, Dr. Icardi and I and other clinicians, program offices within central office are engaged in this work group and are participating as leaders as this work group moves forward.

Dr. BENISHEK. Well, Dr. Icardi, let me ask you then. What input have you provided for this process of, you know, making sure that the VA has an accurate identification process for biologics?

Dr. ICARDI. Well, as you know, biologics, they break into two sides. There is the blood side and then there is the tissue side. And so in the blood bank, we handle mainly blood. And so where we have been involved——

Dr. BENISHEK. Okay. Well, it sounds as if you are kind of backing away from the tissue side and you are talking about just blood. So if it is not Dr. Gunnar and it is not you with the tissue, then where is the doctor who follows the tissue?

Mr. MATKOVSKY. Be very clear here. Both of these gentlemen to my left and my right are involved in this team. This will be a clinically led team. The recommendation will be informed by our clinicians. Our ultimate decision is to the process owner.

Dr. BENISHEK. Well, no, I understand that. It is just that Dr. Icardi answered me and then he kind of was backing away from the tissue issue. I am trying to find out, you know, who is the doctor involved in planning for the tissue. And apparently—am I incorrect? Are you involved in planning for the tissue, how that all works? You said, no, I am involved with the blood.

Dr. ICARDI. Nationally we are involved with the blood. On the local level, there are some blood banks which are involved with tissue. And as GAO noted, it does vary from facility to facility.

Dr. BENISHEK. So who is the doctor that is leading the charge on making sure the tissue is well cared for from beginning to implantation?

Dr. ICARDI. Well, Dr. Gunnar has——

Dr. BENISHEK. All right. Well, I guess my time is up, but I appreciate that you are here this morning. Thank you.

Mr. MATKOVSKY. If I may, just one clarification for Dr. Benishek. Thank you.

Surgery is involved in this process definition. We have gone out. We have canvassed. We have surveyed all of our medical centers. We have looked at what practices we have. And some of our practices have the local blood bank actually managing the tissue. We have a really strong practice that has been in place for decades. We have established processes, established clinical directives with clinical leadership.

Our expectation is——

Dr. BENISHEK. I understand you are saying all that, Mr. Matkovsky, but, you know, you brought two physicians here with you. I asked each of them how are you involved in the process. And Dr. Gunnar said, well, I am in the OR. He limited his answer immediately and then so did Dr. Icardi limit his answer immediately.

So I am wondering who is the physician who is directing, you know, the processing of tissue. And it is not either one of these. Is there someone else? You know what I mean? So that is the problem that I have with what happened here this morning.

Mr. MATKOVSKY. Okay.

Dr. BENISHEK. Very well.

Mr. COFFMAN. We will go into a second round of questions. One question I have, do you, the GAO report discussed the death of a veteran. So it says according to a report—oh, I am sorry, this is in the Journal of the American Medical Association. The kidneys of an Air Force recruit from North Carolina who died from a rabies infection in July, 2013 were transplanted into a Maryland veteran who later died from complications with rabies. Are you acknowledging or denying that that event occurred? Okay. Okay. I understand that that might have occurred at Walter Reed, so.

Mr. MATKOVSKY. I do not, I cannot comment on it.

Mr. COFFMAN. Okay. Let me go into why has the Veterans Implant Tracking System, a vital tool necessary for patient safety, been allowed to stall?

Mr. MATKOVSKY. I do not know that it was allowed to stall, Mr. Chairman. I think it went, finished software development, then it went into testing. I believe, Dr. Gunnar, at the end of fiscal year 2013 it went into testing and some critical defects were identified and then I believe that it sort of got caught up in the IT funding question.

Mr. COFFMAN. According to GAO's testimony, VHA has no oversight ensuring VAMCs check their inventory for and alert affected patients for recall products. Why is no oversight conducted to ensure this safety measure is carried out?

Mr. MATKOVSKY. You know, from 2008 to the end of 2013 there were 13 recalls that were triggered and notified to the VA. Of those, six of them were identified as having an effect on our inventory. So you know, the statement that we have, no mechanism, I do not know that that is entirely accurate because we are able to identify in those six cases for those recalls that we had inventory supply or had inventory supply at some time and initiated a local recall process.

It is correct, however, I want to be clear, that managing the inventory and having greater granular control can be improved with a better tracking system.

Mr. COFFMAN. According to GAO, VA does not ensure that biological implant vendors are registered with the FDA. Is not a simple verification important for patient safety?

Mr. MATKOVSKY. Yes. In so many words, it is.

Mr. COFFMAN. Very well. Mr. Walz.

Mr. WALZ. No further questions.

Mr. COFFMAN. No further questions? Dr. Roe? No further questions. Dr. Huelskamp, no further questions. Well very well, thank you very much, panel, for your testimony.

On our second panel we will hear from Ms. Marcia Crosse, Director of Healthcare for the Government Accountability Office. Your complete written statement will be made part of the hearing record. Ms. Crosse, you are now recognized for five minutes.

STATEMENT OF MS. MARCIA CROSSE

Ms. CROSSE. Thank you. Chairman Coffman and members of the committee, I am pleased to be here to discuss our work on the safety of tissue products used at the Veterans Health Administration. In fiscal year 2013 approximately 59,000 tissue products were used to provide care to veterans at VA medical centers. The tissue products most commonly used by VHA are bone and skin grafts.

While tissue products may provide valuable methods to sustain and improve quality of life, there are also risks that they can transmit a communicable disease from a donor to a recipient, potentially resulting in complications. The Food and Drug Administration, FDA, is responsible for regulating the manufacture of tissue products. These products are generally regulated under FDA's human tissue regulations, or under FDA's medical device regulations. Establishments that manufacture tissue products must register annually with FDA and must follow applicable regulations, including reporting certain adverse events and following good manufacturing practices.

Although VA relies on FDA to ensure the quality of its tissue vendors, VA policies do not require that a vendor's FDA registration status, an important component of federal oversight, be checked for most purchases. VHA officials told us that for open market purchases the agency does not require purchasing staff and contracting officers to check the FDA registration status of tissue product vendors. Open market purchases account for 57 percent of the tissue products that are procured with purchases made from several hundred different vendors.

For the remaining purchases made under fewer than a dozen federal supply schedule contracts, VA does check vendors' registration

status for tissue products regulated as medical devices. However, there is no policy requiring staff to check a vendor's registration status for products regulated under FDA's human tissue regulations.

It is important to note that VHA has not found evidence that it has received contaminated tissue products. It is often not possible to definitively attribute post-surgical infections to a tissue product and it is not uncommon for such infections to occur even in the absence of tissue use. In the past five years VA has notified its medical centers of 13 recalls for tissue products and these recalls were generally issued because of the possibility of contamination, not because of known contamination.

When a recall does occur VHA's ability to identify and track recalled tissue products in its inventories may be limited by poor inventory management practices. The medical centers are required to search their inventories for any recalled products that have not been used. But GAO and the VA OIG have previously reported concerns with the completeness and accuracy of VHA's inventory data and have made recommendations for improvement.

Further, while VA medical centers are also responsible for accurately identifying all recalled tissue products that have been used, identifying implanted tissues may be a challenging task for the medical centers to accomplish. Officials stated that it is difficult to search for information on tissue products that have been implanted in the operating room in part because there is no automated search capability. We also found that VHA conducts no oversight to ensure that these checks of patient records are performed.

VA is taking steps that may improve its ability to track tissue products. For example, VA officials told us that the agency is continuing development of a Veterans Implant Tracking and Alert System, VITAS, which was created to track and retrieve identifying information on surgical implants, including tissue products. In addition, the agency told us that it established a working group to determine the feasibility of utilizing scanning and tracking technology to automatically upload tissue information into patients' medical records.

In summary, VA's recent actions may improve VHA's ability to identify tissue products both in inventories and used to treat veterans. Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions that you or members of the subcommittee may have.

[THE PREPARED STATEMENT OF MARCIA CROSSE APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Ms. Marcia Crosse. I have got a few questions. Some tissue products have already been implanted, injected, or applied by the time a recall occurs. How does VHA ensure that veterans who have been the recipient of such products are identified and notified?

Ms. CROSSE. VHA officials have told us that it is very difficult for them to identify the patients who have received those products. For the tissue products that are implanted in an operating room, VA staff required to enter identifying information about the source and lot number of that product into the patient's record. But it is

manually entered and it is not searchable except by pulling up a text field. So someone must actually go through each patient record to determine if a relevant product implanted. For the outpatient clinics it is even less clear how the information could be tracked.

Mr. COFFMAN. Are the steps VA medical centers take to notify patients of a product recall sufficient to enable prompt identification?

Ms. CROSSE. It is not clear. As I said, it is not clear that contaminated tissues have actually been implanted into patients in VA medical facilities. There have been a small number of recalls. I would like to clarify that among those 13 recalls, for six of them VA identified the product at 27 different facilities. The remaining seven recalls were sent out because there was a belief that the VA had purchased these products. They did not find any. Whether that meant they had already been used or had expired, we do not know. Regarding the steps to actually identify patients, I am not aware that there have been any notifications given to patients that they have received a contaminated tissue. VA has told us they are not aware of any cases of such contamination occurring.

Mr. COFFMAN. Ms. Crosse, what is the problem with VA medical centers operating room staff entering implant serial and model numbers into medical records by hand?

Ms. CROSSE. You have the potential for error, just simple transcription error by, someone having to type something in. In addition it is not entered into something that is automatically searchable. It is in a field where you actually have to go back in and read it and compare it to the product that you would be looking for. It is not something like a bar code that is automatically read into the record.

Mr. COFFMAN. Okay, thank you very much. Mr. Walz?

Mr. WALZ. Well thank you, Mr. Chairman. Thanks, Ms. Crosse. Is VA's purchasing and tracking of biological implants the same as private industry?

Ms. CROSSE. We have not looked at private industry. Some of the same problems exist. There is a new system that is coming online for those tissue products that are regulated as medical devices, the unique device identifier system that is going to be used by facilities throughout the country, VA or private. There is not a similar system in place for identification for biologics that are regulated as tissue products. I think each individual facility has been and will continue to be making its own decisions about what kind of system they have to track.

Mr. WALZ. Maybe Mr. Wilton can help me with that. The reason I keep bringing this up, and I think one of my colleagues mentioned it, we need these facilities to be the best. When my folks at Mayo Clinic tell me that the cardiology at Mayo, Minneapolis, is the best in the world, that is a good thing. That is the way it should be. I keep bringing this back up because it is important holistically as we approach medical reform to understand what the private sector is doing, where they are doing it better and where they are doing it less. And I understand this committee's scope of responsibility as the VA and we are exercising that.

I bring this in to see if we can learn from each other and I know we do that often. And it seems like this would be one of those

issues where that would be pertinent information, so we are not operating in a vacuum.

My next one is how will you, and maybe it is not you, maybe it is in conjunction with the IG to follow up on your report, how will you follow up regarding the recommendations you made in the 2014 report here?

Ms. CROSSE. GAO does follow up routinely. We follow up at least annually with the agency to determine what actions have been taken to make changes in accordance with the recommendations that we have made. We publish an annual report giving the status of recommendations that is available on GAO's website. We also track recommendations for at least five years.

Mr. WALZ. Will our veterans be safer if they follow your recommendations?

Ms. CROSSE. We believe that those recommendations are grounded in the need for actual changes to occur. That it will improve the care that is given to veterans if these changes are made in VHA's inventory management practices.

Mr. WALZ. And I for one, I do appreciate, and I think Dr. Huelskamp was hitting on something important, and I was curious too about his questions on how this worked. I do think it is admirable that there is going to be a connection to whether these things are followed through with, whether this report is implemented, to someone that we can address. So I want to highlight that, though. But he did bring up an interesting point, is who is going to make that ultimate decision? That would be an important thing. Now you said the Secretary. But I do like this, that all of us in conjunction here, because the ultimate goals is accountability for veteran safety. And so now your report, and they are working with it, and they are adding back, and if the private sector can add anything which we will hear from our next panel, so that is our goal. So I am appreciative of that. And with that, I will yield back the remainder of my time.

Mr. COFFMAN. Thank you, Mr. Walz. And just a very quick point, I think, that in the private entities as you mentioned, Mr. Walz, I think that families if there is a lapse in patient safety have recourse through the court system where our veterans rely on us. Dr. Roe?

Dr. ROE. Thank you. And just to dovetail on what Mr. Walz was saying, I really appreciated Mr. Matkovsky, that is the first time since I have been here in five-and-a-half years that someone has said the buck stops here. And I appreciate that. And that fact that you are going to put yourself at some financial risk if you do not get this done, the criteria done and so forth, not completely implemented, I understand that, by the end of the year. So thank you for that.

Ms. Crosse, a couple of things that just looking here, and the more I delve into this the more I realize it is not just the VA, this is a systemwide, perhaps we will hear from our third panel what is going on in the private sector. But it is a little disconcerting that the FDA would approve a tissue bank and then not go back and look at it for several years to see if they are up to standard or doing what they are supposed to. I think that is something that started my wheels turning a little bit. That your report pointed out

to me a deficiency not just in VA. They cannot help what the FDA does. So maybe we need to take another step toward that direction. Would you agree with that?

Ms. CROSSE. The FDA has a risk-based system that they use for tissue products. They also have a risk-based system that they use for making determinations about inspecting medical device establishments and drug manufacturers. The data that it provided to us indicated that it had inspected about a quarter of the tissue banking facilities that were registered with it in the last fiscal year. About 600 inspections had been done out of about 2,500 or 2,600 registered establishments. That actually is in line with or perhaps somewhat higher than the inspections they are performing for medical device establishments and for drug manufacturers. We previously put out a series of reports on this topic and FDA has begun to shift its inspections because it was generally inspecting drug manufacturers domestically and not abroad. And so it has been shifting where it is targeting its inspections and trying to target on those that are manufacturing the riskiest products. I cannot speak to whether it is an appropriate frequency, but that is the frequency FDA is inspecting with the resources it has.

Dr. ROE. Well I think the thing when you see FDA approved, and they have a great reputation, the FDA does, for looking after safety. And quite frankly what we have heard today is that these, so that our viewers out there understand, that for the most part this is very, very safe and very beneficial. But there are holes in there that we need to plug up and make sure. Because if you are a patient, one patient, I mean that young veteran, I guess active duty, who got a kidney transplant, that was 100 percent for him that he got rabies and died because of that mistake that was made. So as a physician, we have got to be right every time. And the folks that are providing, or as every time that we can. And the systems that are providing this material for us, they have to be right on nearly 100 percent perfect. And obviously errors could be made. But 57 percent of 341 different vendors the VA used that made these small purchases that were not, as I understand it, we did not check the FDA. And open sources, I heard you say they did not check the FDA status. So that means a lot of those never got checked. We just made an assumption it was safe.

Ms. CROSSE. We do not know if VA checked.

Dr. ROE. Do not know, okay.

Ms. CROSSE. And I think that is a concern. There is no policy that requires that a check be made. Unlike the federal supply schedule purchases, where actually part of that process requires that VA check the FDA registration status for establishments making products that are regulated as medical devices, there is no requirement for the small purchases that are made, the open market purchases. Similarly, even for the federal supply schedule purchases there is no required check in place to ascertain the registration status for the products that are regulated as tissues as opposed to those regulated as devices.

Dr. ROE. And I think the other thing is just because something is FDA approved does not mean it is 100 percent safe. And because it had not been, does not mean it is not either. I think that is be-

cause the clinical outcomes of most of these 59,000 people, and they have had no reported cases, I guess, unless the tracking is——

Ms. CROSSE. There have been adverse events reported to FDA. When FDA has conducted investigations it has positively confirmed two donors from whom contaminated tissues were recovered and that were sent out to facilities. But neither of those instances involved VHA facilities for the confirmed cases. There are recalls. Adverse events are required to be reported to FDA. There are instances in which there is at least the possibility of contamination and FDA wants to have those products recovered from inventory and patients checked. We know that there is a process at VA for recovering from inventory. We are not sure what is happening in terms of checking patient records.

Dr. ROE. And just as I finish, Mr. Chairman, you know it looks like as you pointed out, and human error, and the bar code, that that technology is available. I mean, Harris Teeter knows when I walk in and buy a box of cereal what I bought, and they send me a coupon three weeks later for fifty cents off. So it should be fairly easy to do that. But that is not new technology, it has been around forever. And it would create a line downstream to find out where this came from, where the source was, and you could track it much easier. I think that would simplify it tremendously. I yield back.

Mr. COFFMAN. Dr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman. Ms. Crosse, the question from Mr. Walz was about what is happening in the private sector, how this occurs, and you did not have experience on that, had not compared that. Are you able to compare that to other sectors? The federal government? The DoD has an enormous system. Do they use non-FDA approved items? Do they purchase off the schedule? Can you shed any light on comparison there?

Ms. CROSSE. I am afraid our review did not focus on what was happening in other federal health care facilities. We only were looking at what was happening at the VA.

Dr. HUELSKAMP. Okay. And I appreciate that. I understand the limits on that. You did look at the VA's OIG study in March of 2012?

Ms. CROSSE. Yes.

Dr. HUELSKAMP. Where it indicated that informal tracking systems, I am not sure how well informal tracking systems work, and if you are trying to look at a recall, you are trying to look at adverse effects, they cannot even track the product on the shelves much less the patients. I mean, so if I asked the question, as you saw earlier, it is, well, we do not know. We actually do not know what we do not know. Is that an accurate assessment of an informal tracking system that no one knows for sure what is there and it is just a best guess?

Ms. CROSSE. According to the IG's report, different facilities had their own individual systems in place for tracking. There was not a centralized system. It could not be accessed by VHA systems. But as I understand it, that is part of the changes that are being put in place that Dr. Gunnar spoke to, specifically for those products that are implanted in operating rooms. I am not sure what is being done for the outpatient facilities.

Dr. HUELSKAMP. And you reviewed the report. Do you know if this has been implemented? Or how far along they are in fixing this informal tracking system which is the basis for saying that no adverse events have been reported on the use of these tissues?

Ms. CROSSE. Our understanding is that the comprehensive inventory management system is part of what was discussed earlier and the last update we had was that it is supposed to begin to come online in 2015.

Dr. HUELSKAMP. Okay, so it is still not there. So one other question I would ask of the VA I would like followed up on is populating the NCPS system. Or NCPS, in your opinion is that sufficient? Can you describe for the committee how it is determined that you do a recall? Again, I presume actually if the FDA had a recall that did not mean that VA actually initiated a recall either. They were not always the same. Can you describe that a little bit more, about an internal VA system that everything is hinging on in terms of this report?

Ms. CROSSE. The NCPS system is used to try to track recalled products that may still be in inventory. There is a centralized system that allows NCPS to go out, that covers the VAMCs, and that would allow NCPS to determine whether or not those products had been procured at different facilities so that they could then have the facility go and remove that product from the shelf. There have been some concerns about the accuracy of all the information that is in that system but nevertheless that at least provides a centralized source. The gap I think occurs because VHA does not have oversight of what has happened for the tissues that have been used and that may be covered by that recall. That is where the VAMCs are individually responsible for checking individual patient records to make a determination of whether or not someone received an implanted product that had been recalled and whether notification to that patient is warranted.

Dr. HUELSKAMP. And you do also note that although the NCPS tracks and responds to recalls, at least partially I would say, they do not track warning letters. Can you describe a little bit more why those are ignored by the system?

Ms. CROSSE. VA told us that the information in warning letters is really not that helpful for them because the warning letters that FDA puts out are really focused on changes that a company needs to make in order to be in compliance with FDA requirements and would not necessarily result in products having been distributed that were contaminated or otherwise needed to be subject to a recall. There have only been a small number of warning letters to tissue establishments in the last several years. But the VA officials indicated they did not believe that that would provide them with actionable information.

Dr. HUELSKAMP. Even though in one case the FDA issued a warning letter to a vendor and the VHA did not know about that, and obviously did not respond to that because they only respond to recalls. Ms. Crosse, I appreciate the report and I would suggest in the future, and like Mr. Walz indicated, you know, comparison to what is going on in the private sector. But I also would like to see as well, I mean, comparison to the DoD. Because the NCPS does use DoD information. I am not for sure how that works here. But

it seems to be not in any formal manner. But in your report you do mention in a footnote, you talked to visiting officials, you talked to FDA, DoD, and tissue vendors, and I am not sure if there is any formal process for doing that.

But last, really quickly, the non-FDA issue——

Ms. CROSSE. Yes.

Dr. HUELSKAMP [continuing]. And we do not know what we do not know, and we could not prove that. The recalls, obviously if FDA is going to have a recall, it is not going to apply to non-FDA vendors in this case. And I am not sure how you track that, or you can indicate you tried?

Ms. CROSSE. Most recalls are actually not directed by FDA. Most of the recalls that occur are voluntary recalls that are initiated by the vendor themselves. There have only been one or two instances where FDA has actually mandated that a recall occur. That is not uncommon across the board for all types of medical products. Most recalls are voluntary.

Dr. HUELSKAMP. I appreciate it. I yield back, Mr. Chairman.

Mr. COFFMAN. Our thanks to Ms. Crosse. You are now excused.

I now invite the final witness to the table. On our third panel we will hear from Mr. Frank Wilton, Chief Executive Officer of the American Association of Tissue Banks. Your complete written statement will be made part of the hearing record. Mr. Wilton, you are now recognized for five minutes.

STATEMENT OF MR. FRANK WILTON

Mr. WILTON. Chairman Coffman, Mr. Walz, and distinguished members, the American Association of Tissue Banks, or AATB, would not be here today if it was not for the U.S. military. The very first tissue bank in the U.S. was the United States Navy Tissue Bank, which was established in 1949 by Dr. George Hyatt. In 1976, Dr. Hyatt and his colleagues helped found the American Association of Tissue Banks. Recognizing the increasing use of human tissue for transplant, these individuals saw the need for a national organization to develop standards, promote ethics, and increase donations.

Beyond the historical significance, AATB accredited tissue banks continue to focus on the needs of veterans. As you know, many military personnel serving in Operation Iraqi Freedom and Operation Enduring Freedom have received severe burn injuries due to the use of IEDs. If necessary, donor skin may be used as a life saving dressing. AATB accredited tissue banks have helped ensure that veterans have access to these life saving dressings, as well as other biological implants necessary to relieve pain, restore mobility, restore sight, and save limbs.

With that in mind, thank you for the additional opportunity to come before you today in support of the "Biological Implant Tracking and Veteran Safety Act of 2014." This critical legislation directs the Secretary of Veterans Affairs to adopt a standard identification system for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the success of the implementation of the unique device identifier, or UDI, this legislation will ensure that biological implants used within the Department can be appropriately tracked from a human tissue donor all

the way to the recipient. This critical capability for track and trace efforts will enhance patient safety, expedite product recalls when necessary, assist with inventory management and improve overall efficiencies.

This legislation takes a bold step to expand UDI to all tissue products. In addition to human tissue devices which are already covered by the UDI, the legislation adds another product category: certain biological implants or, as termed by the Food and Drug Administration, 361 human cells, tissues, and cellular tissue-based products, or HCT/Ps. While many of the biological implants do have company specific bar coding information, by requiring a standardized format for those bar codes as outlined in this legislation, it will be easier for the Department of Veterans Affairs medical facilities to utilize universal bar coding conventions and to realize the full benefit of a unique identification system. Finally, by applying a system which has been developed for devices to biological implants such a solution should also be applicable to other health care settings and other health care systems such as the Department of Defense health care system and the private sector.

While I understand the committee's skepticism in requesting that the VHA attempt a VITAS-like enterprise in this legislation after failing to do so before, I would note that a lot has changed since 2008 when the VHA first envisioned VITAS. First, there is now a UDI benchmark which allows those developing the necessary software for data capture to move from a design incorporating dozens of bar code technologies to only three. In addition the VHA is not alone in trying to develop a system for integrating UDI like information directly into the medical record. For instance, the Office of the National Coordinator for Health Information Technology is currently focused on the ways in which the UDI can be better operationalized to ensure its adoption into key standards. As part of those efforts ONC is initially focusing on implantables, the very focus of the legislation we are discussing today. Therefore the VHA will not be attempting to establish such a system alone, but can partner with other governmental agencies to ensure its success.

For those of you unfamiliar with my organization, the American Association of Tissue Banks is a professional, not for profit scientific and educational organization. It is the only national tissue banking organization in the United States and its membership totals more than 125 accredited banks and approximately 850 individual members. These banks recover tissue from more than 30,000 donors and distribute in excess of two million allografts for more than one million tissue transplants performed annually in the U.S.

Finally when I last discussed this legislation before the committee I noted my concern that the draft legislation lacked a requirement that biological implants purchased by the VHA be subject to appropriate accreditation standards. It is my understanding that those concerns have been addressed in the latest version of the legislation by requiring accreditation by AATB or a similar accreditation organization. Thus with this change the VHA will be joining the ranks of leading medical centers of excellence which currently require all tissue to be sourced from AATB accredited tissue banks.

AATB strongly supports this legislation and urges the committee to favorably report it out of committee. This ends my prepared remarks and I would be happy to answer any questions.

[THE PREPARED STATEMENT OF FRANK WILTON APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Mr. Wilton. Mr. Wilton, is it common for biological implant vendors to receive FDA warning letters?

Mr. WILTON. No. In fact it is fairly rare, Mr. Chairman. We went back and looked back to fiscal year 2000, and there were 43 recalls that were issued within that roughly 15-year period. To put it in perspective the FDA, looking at all the different areas it has jurisdiction over, issued 45 in January of this year alone. However, it is a very serious thing that our banks take with the utmost concern.

Mr. COFFMAN. Mr. Wilton, what is the benefit of the UDI or a standardized identification system for VHA?

Mr. WILTON. As I remarked, in my comments, Mr. Chairman, it is largely due to tracking and tracing so we can track it from the donor all the way to the recipient. I think from the VHA's perspective it will be helpful for inventory management, be useful if there is in fact a recall and overall improve efficiency within the VHA system.

Mr. COFFMAN. What are some concerns with the use of tissue distribution intermediaries?

Mr. WILTON. Sure. TDIs are sort of on the back end of the system, if you will. We went back and looked at FDA registration data and as best we can tell only about 16 percent of the TDIs are in fact accredited by AATB. So the question becomes, are they maintaining the standards they need to in order to make sure that the tissue is stored appropriately and it is distributed appropriately? So the short answer is, we do not know for sure. Only the ones that we accredit can we speak for.

Mr. COFFMAN. Mr. Walz.

Mr. WALZ. Thank you, Mr. Chairman. Thank you, Mr. Wilton. Just two quick ones here for you. From your approach on this, and you have been hearing some questions as you have been here, how does the VA look compared to those other centers of excellence you are looking at in terms of where they are going in this?

Mr. WILTON. Yes, I think this is a terrific effort. And as I said in my testimony, we hope that once this is implemented it can get beyond the VHA to DoD and to the private sector. I think the big change is our tissue banks track and trace all their tissue but there are a lot of different bar code systems. With the FDA's guidance there will now be three, and I think it will be much easier for the VHA to implement those systems and then hopefully go much beyond that.

Mr. WALZ. And that will hold true both in the private sector also for them to follow that?

Mr. WILTON. Yes. Yes, sir.

Mr. WALZ. So this will help, will this help lead and push into that?

Mr. WILTON. Absolutely. I think it is a terrific step for the VHA to take the leadership role in this, and we are happy to work with them.

Mr. WALZ. That is great. And from today's testimony, what did you hear that most concerns you, if there is something you could hear amongst this testimony? Just trying to educate us and understand some of——

Mr. WILTON. Sure. I mean, again, the good news is, the FDA registration issue is one that clearly concerns the committee. AATB accredited tissue banks are registered with the FDA. You had some concerns about the frequency of inspections. When you are accredited by AATB, we inspect each one, and there is a three-year period where we reinspect. So between the FDA and AATB, there are many more inspections. And we just think that our veterans deserve the best, and we feel strongly that AATB accredited tissue banks provide the best.

Mr. WALZ. Okay. Because what you are hearing, and I hear when it got explained further, we are always going to err on the side of cautiousness towards our veterans. So when we hear that there is a possibility I think my colleague was bringing up a good point. I understand it is not proving the negative type of situation. He was just asking, you cannot in all, 100 percent confidence, tell us this is happening. That concerns us. So I think it is important for us to understand what those steps are and how they are there and how we make that clear as we go back and assure our constituents that they are protected. And so with that, I yield back.

Mr. COFFMAN. Thank you, Mr. Walz. Dr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman. Mr. Wilton, your association, is that the entirety of the industry? Or are there some other competing associations?

Mr. WILTON. I am not aware of any others.

Dr. HUELSKAMP. Okay.

Mr. WILTON. And in doing the analysis we feel that about 92 percent of all the tissue that is recovered and processed in this country is done through AATB accredited tissue banks.

Dr. HUELSKAMP. Mm-hmm. And the other eight percent, is that through another accredited organization? Or——

Mr. WILTON. I am not aware of another organization.

Dr. HUELSKAMP. Okay. What happens in that eight percent, then? Can you describe that? No one knows, is that——

Mr. WILTON. I think you are correct, sir. No one knows.

Dr. HUELSKAMP. Okay. Okay. In your experience, I asked a question of both the previous panels. Are you able to compare the VA, compared to say the DoD, or other federal agencies? And can you describe that comparison, what it looks like for the committee?

Mr. WILTON. I think there are challenges in all health care settings once the tissue actually gets to the consignee, the hospital or the doctor. I think it is a universal problem. And as I said earlier, I think it is terrific that the VHA is considering taking a leadership role in this.

Dr. HUELSKAMP. So does the DoD track this? Do they have an informal tracking system? Do they have a formal tracking system——

Mr. WILTON. My understanding——

Dr. HUELSKAMP [continuing]. Next largest system?

Mr. WILTON. Yes, my understanding is they do it the same way that the VHA does.

Dr. HUELSKAMP. Which is——

Mr. WILTON. Again, it is a manual process, not a bar coding process. So having it in an automated sense I think would make great strides for both DoD and——

Dr. HUELSKAMP. Do you believe is it standardized and manual or——

Mr. WILTON. As I alluded to, there are going to be three different systems that the FDA has approved to track and trace. And I think the VHA and DoD will be able to adopt them, and our members will obviously provide those as well.

Dr. HUELSKAMP. And my concern was not so much necessarily with the manual aspect of that. It is the fact that in the VA it was not standardized.

Mr. WILTON. My understanding is it is not, sir.

Dr. HUELSKAMP. Yes. And it was informal, which means it is not formal. But is the DoD, in your opinion is it informal as well——

Mr. WILTON. My understanding is that they operate on a similar fashion.

Dr. HUELSKAMP. Okay. Well that is particularly troubling. So if there is a recall, how does the DoD handle that?

Mr. WILTON. I am not aware of that, sir.

Dr. HUELSKAMP. You are not aware? So I presume you have members that work with the DoD? I would appreciate some follow up on that from your, how they handle that——

Mr. WILTON. We would be happy——

Dr. HUELSKAMP [continuing]. I know we are talking about the VA. But if we are going to talk about that you think the VA system that they are talking about implementing would be the best, that raises a concern with me as well. Mr. Chairman, I yield back. Thank you.

Mr. COFFMAN. Thank you. Dr. Roe. Mr. Wilton, thank you so much for your testimony. You are now excused.

At this time I would like to give VA, if they would like to respond to any of the comments in the prior two panels? Okay, seeing none, today we have had a chance to hear about many problems occurring with VA sourcing, procurement, and tracking of biological implants. From the testimony provided and questions asked today, I am alarmed at the great risk of harm our veterans face when they receive a biological implant from the VA. As such this hearing was necessary to accomplish a number of items: to identify the reasoning for VA's questionable procurement and tracking practices involving biological implants; to require VA officials to explain their inadequate response to these obvious deficiencies; and to determine what steps are being taken to correct these issues and improve the care provided to our veterans.

I ask unanimous consent that all members have five legislative days to revise and extend their remarks and include extraneous material. Without objection, so ordered.

I would like to once again thank all of our witnesses and audience members for joining in today's conversation. With that, this hearing is adjourned.

[Whereupon, at 11:41 a.m., the subcommittee was adjourned.]

WRITTEN STATEMENT OF
PHILIP MATKOVSKY
ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH
FOR ADMINISTRATIVE OPERATIONS
VETERANS HEALTH ADMINISTRATION
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

April 2, 2014

Mr. Chairman, Ranking Member Kirkpatrick, and members of the Committee, thank you for the opportunity to appear before you this morning to discuss the Department of Veterans Affairs' (VA) sourcing, procurement, and oversight of its biological implant purchases, including implant tissue. I am joined today by Dr. William Gunnar, National Director of Surgery, and Dr. Michael Icardi, National Director of Pathology and Laboratory Medicine Services.

Background: Industry

Over the last 8 to 10 years, utilization of biological implants, including implant tissue, has grown significantly resulting in the doubling of value of the biomaterials market since 2004. However, the field of biological implants continues to rapidly evolve, with new advancements in tissue fabrication, nomenclature standardization, and industry governance.

Accomplishments in Procurement

On September 30, 2013, the Veterans Health Administration (VHA) successfully completed its transition of procurement duties from prosthetics purchasing agents. This transition resulted in the removal of warrants from staff who were not contracting officers. This transition also marked the final such transition for VHA – meaning that, as a rule, procurements above the micro-purchase threshold are now performed by

warranted contracting officers. In the area of prosthetics alone, VHA contracting officers have conducted 38,742 procurements throughout the first quarter of fiscal year (FY) 2014. Despite our ability to effectively complete this transition, it has not come without its own challenges, and our procurement and prosthetics leadership teams convene weekly to review timeliness of procurement actions to ensure Veterans receive their needed prosthetic items, to include biological implants, on a timely basis.

Directive Regarding Procurement of Prosthetics Appliances

Title 38, Section 8123, grants broad authorities to the Secretary in the procurement of prosthetics appliances. Notwithstanding this broad authority, VHA, working with our agency's counsel, has integrated our prosthetics purchasing authority with Federal Acquisition Regulations (FAR) and VA Acquisition Regulations (VAAR) provisions. In this integration, the 8123 authority is employed as a statutory basis for a FAR Part 6 justification for other than full and open competition. What this means in practice, is that if a clinician who has been trained on a particular product has felt comfortable with that product, then she can be assured that a Government procurement official will not restrict her from selecting and using a product with which she feels competent for her patients. This application of our prosthetics authority enables our clinicians to make choices based on their medical determination of the best choice for their patients.

VHA Acknowledges Much Yet to Be Done

In complicated systems, it is always possible to improve our management and tracking controls. For more than 5 years, VHA has been able to track blood products to patient records using a barcode system, and similarly VHA Cardiology has been able to track implants to patient records. In 2011, VHA's Surgery Program implemented an implant tracking capability that also allows tracking of implants to patient records. This foundation of detailed clinical inventory management will be leveraged to provide a single comprehensive tracking mechanism that will incorporate biological implants. However, we acknowledge that we can significantly improve our tracking and inventory

management of biological implantables, including tissue implants. In 2013, the Food and Drug Administration (FDA), published a final rule requiring that most medical devices distributed in the United States carry a unique device identifier, or Global Unique Device Identifier Database, and that information concerning each covered device be submitted to the global unique identification database. The rule contains staggered compliance dates. With the advent of this new identifier, systems should be able to track a specific item and associate it with the manufacturer. This tracking will enable improved adverse event tracking and will further enable greater automation in product recalls. Further, complying with FDA's Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products and Guidance for Current Good Tissue Practices, along with standards from accreditation agencies such as the American Association of Tissue Banks, Advancing Transfusion and Cellular Therapies Worldwide, and the Joint Commission, will assist in providing greater assurance over the sourcing, tracking, storage, and management of Biological implants.

Work Team and Anticipated Recommendations

With the more recent developments in the biological implants industry and in reaction to external audits and reviews, VHA has established a work team to identify improvements to our sourcing, management and control of biological implants. This work team has been evaluating the processes currently employed by our facilities and has begun development of a proposed process to effectively manage our biological implants in a standard manner across all facilities. This work team is expected to complete its review and recommendations in the third quarter of FY 2014. We will review this team's work product and we will then begin the process of establishing a standard protocol, to include establishment of the common clinical service to manage inventory in each of our facilities.

Whether this inventory management function can be accomplished with existing technologies already deployed in VHA or with commercially available systems will be determined at the conclusion of the work team's analysis. We do, however, expect to

deploy automated tracking of biological implants similar to the effective automation systems we have been using for some time now for blood bank requirements.

We have similarly charged a work team to develop a set of new, national contracts for biological implants. This work team is in the phase of procurement known as development of requirements. The work team is comprised of clinician leaders, logistics specialists, and prosthetics specialists. We fully expect our new procurement packages to establish more stringent quality standards than previous schedule contracts. We anticipate the solicitation phase of these new procurement actions to be initiated prior to the end of FY 2014.

Must Achieve Balance - Enable Physicians to Make Informed Selections

Our core mission in VHA is the delivery of timely, quality, patient centered care. Our systems must apply controls, where appropriate, to further that core mission. We acknowledge we must continue to seek, define, and implement improvements, to our management, tracking and control of biologics items. We are committed to making the necessary changes to our policies, practices, and systems to improve. We must, however, ensure that our procurement system achieves balance and complies with all applicable Federal Laws and regulations while ensuring our physicians, whom we trust with the most critical decisions, are able to apply clinical discretion as they provide Veterans with individualized health care.

Mr. Chairman, this concludes my testimony. I appreciate the Committee's continued interest in the health and welfare of America's Veterans. At this time, I am prepared to answer your questions.

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EDT
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VETERANS' HEALTH CARE

Oversight of Tissue Product Safety

Statement of Marcia Crosse
Director, Health Care

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee:

I am pleased to be here to discuss our work on the safety of tissue products used at the Veterans Health Administration (VHA), within the Department of Veterans Affairs (VA). Tissue products can be used to repair parts of the body, improve function and feeling, and restore appearance. In fiscal year 2013, approximately 59,000 tissue products were used to provide care to veterans at VA medical centers (VAMC).[1] Some of the more commonly used tissue products by VHA are bone and skin grafts.[2] Some tissue products, such as bone or tendon, may be permanently implanted into veterans in the operating room. Others, that are temporary in nature because they degrade over time or are absorbed into the body, may be applied or injected in outpatient clinics. These include skin grafts used in wound care and collagen injections.

While tissue products provide valuable methods to sustain and improve quality of life, there are also risks that they can transmit communicable disease from the donor to the recipient, potentially resulting in severe complications.[3] Transmissible pathogens can include viruses, bacteria, parasites, and fungi. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, is responsible for regulating the manufacture of tissue products to help ensure that these products are safe and to prevent disease transmission.

VHA, which oversees all VAMCs, considers tissue products to be a type of surgical implant for purchasing purposes.[4] VHA defines these as

[1]For purposes of this testimony we refer to VAMCs to include the associated outpatient clinics.

[2]Other types of tissue products used by VHA include cartilage, collagen, connective tissues, heart valves, ocular tissues, and tendons. While tissue products can be derived from humans or animals, the majority of the tissue products used by VHA are derived from humans. Human tissue products that are derived from living or deceased donors are known as allografts. A patient's own tissue can also be used for a surgical reconstruction procedure—these are known as autografts. Our work did not include a review of VHA's use of autografts.

[3]Some tissues may be more prone to communicable disease than others, depending on the tissue type and processing methods used to prepare them for implantation, application, or injection.

[4]VHA codes tissue products as biological implants—a type of surgical implant—in its National Prosthetics Purchasing Database.

prosthetics, which include all items that support or replace a body part or function. At recent hearings before this subcommittee, concerns were raised about VA's oversight of surgical implant purchases and the agency's ability to identify veterans who received an implant that is being recalled by the manufacturer or FDA. My remarks today will address the following two areas: (1) whether VHA received tissue products that may have been contaminated and (2) VHA's safeguards to prevent the receipt and use of contaminated tissue products, including VHA's ability to ensure the quality of its vendors and to respond to recalls of tissue products.

My remarks today are based on information we collected through reviewing agency documents and interviews with VA, VHA, and FDA officials. Specifically, to examine evidence related to possible receipt of contaminated tissue products, we reviewed VHA's analyses of purchasing data from its National Prosthetics Purchasing Database (NPPD) and NPPD data on tissue products used for treatment of veterans. We also reviewed VHA's and FDA's analyses of data on recalls and reported adverse events related to tissue products, including outcomes of these events. To determine the actions VHA takes to prevent the use of contaminated tissue products, we interviewed VA and VHA officials and reviewed documentation on VA's processes and requirements related to tissue product safety. For example, we reviewed certain aspects of VHA's oversight of and purchasing from tissue product vendors, such as whether VHA requires its vendors to have an active registration with FDA. We also reviewed VHA's tracking of, and response to, manufacturer recalls of tissue products. In addition, we interviewed officials from the VA's Office of Inspector General (OIG) regarding its related work on this topic. Our work focused on the policies and procedures at the VA and VHA level. Our work did not focus on VAMCs, though VAMCs may have their own policies and procedures, such as those related to purchasing and responding to recalls.

To assess the reliability of the data used to prepare this statement, we gathered information from VHA and FDA on their data collection methods, including controls used to help ensure the data recorded is accurate and complete. We recently reported that NPPD data has some inconsistencies and errors that are attributable to data entry errors and

omissions.[5] In our work for this statement, we also found data errors in NPPD data on VHA's tissue product vendors, such as missing or incorrect values. These errors could affect the accuracy of VHA's reports of its tissue product purchases made through contracts with vendors and purchases made on the open market.[6] However, NPPD data represent the best information available and are the data VHA relies on to determine the vendors it uses and to manage its purchasing. As a result, we found that these data were sufficiently reliable for our use in preparing this statement.

We conducted this performance audit from January 2014 to April 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We shared the information we used to prepare this statement with VA and FDA. After reviewing this information, VA and FDA provided us with technical comments, which we incorporated as appropriate.

Background

VHA operates one of the largest health care delivery systems in the United States, providing care to more than 6 million veterans annually. Its health care system includes 151 VAMCs nationwide that offer a variety of outpatient and inpatient services, ranging from routine examinations to complex surgical procedures. VHA also provides outpatient care at more than 800 community-based outpatient clinics.

Like other health care providers, VHA relies on FDA to regulate the manufacture of tissue products to help ensure the safety of such products marketed in the United States. Depending upon whether the tissue

[5]GAO, *VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement*, GAO-14-146 (Washington, D.C.: Jan.13, 2014), 31.

[6]VA negotiates national, regional, and local competitive contracts with vendors for all types of items—including tissue products. Items that are not purchased from these contracts are referred to as open-market purchases.

product is derived from a human tissue or an animal tissue, different FDA regulations apply.

- Human tissue products: FDA generally regulates human tissue products under a regulation specific to human cells, tissues, and cellular and tissue-based products.[7] Establishments that manufacture human tissue products must register annually with FDA and submit a list of each type of human tissue product manufactured.[8] FDA regulations include requirements for human tissue establishments to screen and test potential tissue donors for relevant communicable disease agents and diseases, report certain adverse events involving a communicable disease, and follow current good tissue practice requirements.[9] Some human tissue establishments may also manufacture products regulated as drugs, devices, or biological products that would be subject to additional regulatory requirements including premarket review, and the adverse event reporting requirements specific to those products.[10] FDA conducts inspections of foreign and domestic human tissue establishments to ensure they are in compliance with applicable regulations.[11]

[7]21 C.F.R. pt. 1271. In this statement we refer to these regulations as FDA's "human tissue regulations." Under FDA regulations, the manufacture of human tissue includes the recovery, processing, storage, labeling, packaging, or distribution of human tissue, and the screening or testing of the tissue donor. 21 C.F.R. § 1271.3(e).

[8]21 C.F.R. § 1271.21(a), (b). Establishments subject to these requirements include a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. 21 C.F.R. § 1271.3(b).

[9]Current good tissue practices are intended to ensure that tissue products do not contain communicable disease agents, are not contaminated, and do not become contaminated. They include requirements related to tissue storage and distribution, labeling, record keeping, and tracking tissue products from the donor to the consignee. 21 C.F.R. § 1271.150.

[10]21 C.F.R. § 1271.1(b)(2).

[11]FDA conducts inspections of human tissue establishments based on available resources and uses certain risk-based priorities when determining which establishments to inspect. In fiscal years 2012 and 2013, FDA inspected 592 and 671 establishments regulated under its human tissue regulations, respectively. FDA officials stated that, due to data constraints, the agency could not determine if all establishments regulated under its human tissue regulations had an inspection. Human tissue establishments that are also regulated under FDA's drug, device, or biologics regulations are subject to inspection requirements under those provisions. 21 C.F.R. § 1271.390.

- Animal tissue products: FDA generally regulates tissue products derived from animals under its medical device regulations.[12] Similar to human tissue establishments, device establishments must register annually with FDA and submit a list of each product manufactured, report certain adverse events that may have been caused or affected by use of one of its devices, and follow current good manufacturing practice requirements.[13] FDA inspects certain foreign and domestic device establishments to ensure they meet required manufacturing standards.[14] Similar to human tissue products regulated as devices, animal products regulated as devices also must meet certain premarket review requirements.[15]

[12]21 C.F.R. pts. 800-898. Some tissue products derived from animals may be regulated as drugs or biological products. 21 C.F.R. pts. 200-499, 600-680.

[13]A device establishment is a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3(c).

[14]FDA is required to inspect domestic establishments that manufacture devices that meet certain risk classifications every two years. 21 U.S.C. § 360(h). FDA is not required to inspect foreign establishments on a specific schedule.

[15]In general, unless exempt by regulation, new devices are subject to premarket review either through the premarket notification process, to determine whether a new device is substantially equivalent to another legally marketed device, or the more stringent premarket approval process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. 21 U.S.C. §§ 360(k), 360e. On January 23, 2014, FDA issued draft guidance related specifically to medical devices containing materials derived from animal sources. FDA stated that although the use of animal derived-material in medical devices is well established, animal materials may carry a risk of transmitting communicable disease when improperly collected, stored, or manufactured. The draft guidance describes the information that should be documented at the manufacturing facility and included in any premarket submissions to FDA.

VHA Data Do Not Show Evidence of Contaminated Tissue Products, Although Attributing Adverse Events to Tissue Product Contamination Is Difficult

While there have been thousands of tissue products used at VAMCs, VHA data do not show evidence of VHA receiving contaminated tissue products. However, it is difficult to attribute adverse events to tissue product contamination. VA's National Center for Patient Safety (NCPS) issues patient safety alerts, patient safety advisories, and recalls to notify VAMCs of possible receipt of unsafe or defective medical products, including tissue products. NCPS, which began operation in 1999, has not issued any patient safety alerts—mandates for action to address actual or potential threats to life or health—or advisories—guidance to address issues such as equipment design and product failure—related to tissue products in the last 10 years, according to NCPS officials.[16] NCPS issues patient safety alerts or advisories for recalls that require specific clinical actions to ensure patient safety. Since NCPS began issuing and recording data on recalls in November 2008, it has notified VAMCs of 13 recalls through September 2013 for tissue products from vendors from which VHA could have received the affected products—none of these recalls have resulted in patient safety alerts or advisories.[17] Each of these recalls could represent the recall of just one product, multiple products, or all products processed within a specific date range from a particular vendor. After NCPS issues recalls, it receives reports from VAMCs on whether recalled products were identified in their inventories—VAMCs do not report to NCPS if any products were used. Of the 13 recalls, 6 resulted in 27 VAMCs reporting back to NCPS that they had identified and removed the recalled products from their inventories. For the other 7 recalls, no VAMCs indicated that they had the affected products in their inventories. None of the 13 recalls were issued for known tissue product contamination. Instead, most were initiated because of the possibility of contamination for reasons such as compromise of product sterility, tissue recovered from donors with risk factors for communicable diseases,

[16]Patient safety alerts or advisories are classified as such based on the severity and frequency of the incident.

[17]NCPS identified recalls related to tissue products through September 30, 2013. The products included in these 13 recalls were obtained from 11 different vendors. NCPS issues recall notifications through VHA's Alerts & Recalls intranet database to ensure that every applicable facility receives them and assigns facilities to review and take any designated actions, such as removing the product(s) from inventories. NCPS does not issue notices for all recalls. According to officials, reasons not to issue a recall notice include FDA reports that the recall is complete or terminated, the vendor reports that VHA did not receive the affected product(s), the product at the time of reporting is expired, or the product was not a remove-from-use (pull off the shelf) recall notification.

incomplete donor records, or manufacturers suspected to have deviated from FDA's current good manufacturing practices.[18]

Further, VHA officials told us that their analysis of VHA data found no evidence of reported adverse events among VHA patients that were caused by contaminated tissue products. Specifically, NCPS officials stated that they searched the NCPS Patient Safety Information System database, commonly known as "SPOT," which did not yield any evidence of proven adverse events being caused by tissue product contamination. SPOT contains root cause analysis reviews (investigations conducted by VAMCs to evaluate the system or process causes of reported adverse events) and patient safety incident reports (patient safety-related adverse events reported to NCPS).[19] Collectively, NCPS officials stated that their search of SPOT encompassed nearly 1 million records over more than 11 years.

Nonetheless, it is also important to note that it is difficult to determine whether adverse events are caused by contaminated tissue products. FDA officials told us that it is often not possible to definitively attribute post-surgical infections to a tissue product, despite thorough investigations of reported adverse events. FDA noted that there may be multiple possible causes of an adverse event, given the several potential sources of infection (e.g., the patient, the clinical setting, or the medical product itself). FDA also pointed out that infections following surgical procedures often occur, even in the absence of tissue use. Adverse events specifically caused by contaminated tissue appear to be rare nationwide. Of the approximately 850 reported adverse events potentially related to human tissue products received by FDA between January 1,

[18]One of the 13 recalls was initiated for reasons other than potential contamination.

[19]All root cause analyses are required to be reported to NCPS. According to NCPS, each VAMC can submit patient safety incident reports to NCPS using a web-based form that is standardized across VAMCs. However, officials cautioned that they rely on personnel in the field to recognize an event as a patient safety-related adverse event and enter it into the system. Since it is a voluntary reporting system, NCPS officials said they would not feel comfortable stating that every adverse event that has happened in all VAMCs is represented in the database. In addition, the level of detail in each report is often not enough to say why an event happened. Besides submitting patient safety incident reports to NCPS, each VAMC maintains its own incident reporting system, which is used by VAMC staff to report information on adverse events. Our review did not include those adverse events maintained in the individual VAMC's reporting systems.

2006, and June 30, 2013, FDA informed us of 2 cases where infection could reasonably be attributed to the tissue product.[20]

VA Does Not Ensure Vendors are Registered with FDA; VHA's Identification of Recalled Tissue Products May Be Limited, Although Recent Actions May Help

VA relies on FDA's oversight of tissue vendors, but VA and VHA policies do not require that staff check tissue vendors' FDA registration status for most purchases. VHA's ability to track recalled tissue products may be limited by poor inventory management practices. We and VA OIG previously have reported similar concerns with VHA's inventory management practices and have made recommendations to improve VHA's ability to accurately identify all recalled products in VAMCs' inventories. Although VAMCs are responsible for checking for all implanted, applied, or injected tissue products subject to a recall, VA and VHA have no oversight to ensure this is done. VAMCs' ability to conduct this check may be limited, but VA has taken steps that may enhance its ability to identify tissue products after they have been used.

VA Relies on FDA Oversight of Tissue Vendors but Does Not Ensure Its Vendors Are Registered with FDA

The VA and VHA policies we reviewed suggest that VA and VHA do not require staff to check tissue vendors' FDA registration status for most types of purchases, despite VHA's reliance on FDA's oversight of tissue establishments to ensure the quality of the tissue products the agency receives. In addition, VA does not conduct additional oversight of its own.[21] Registration is important to ensure that tissue establishments are subject to proper federal oversight. This oversight includes, for example, FDA inspections to determine compliance with regulatory requirements pertaining to tissue product safety, such as testing and screening donors for communicable diseases. It is important to note that, according to officials, VA's vendors could include some distributors who are not required to register with FDA because they never take physical possession of tissue products. VHA has no policies requiring purchasing

[20]The data included those products regulated solely under FDA's human tissue regulations with the exception of cell therapy products or reproductive tissue products, which are tissue products not generally used by VHA. These data did not include tissue products that are also regulated under FDA's drug, device, or biologics regulations and are, therefore, subject to those regulations' adverse event reporting requirements.

[21]We reviewed VA and VHA-wide policies; our review did not include any policies that may exist at the VAMC-level. For example, VAMCs may have established their own VAMC-specific purchasing policies.

staff to check whether these distributors are supplying tissue products from registered tissue establishments. When discussing their purchasing requirements, VA and VHA officials told us that:

- The majority—51 percent—of tissue product purchases were open-market purchases below the Federal Acquisition Regulations (FAR) micro-purchase threshold of $3,000 in fiscal year 2013; pursuant to VHA's purchasing processes, these purchases are made by local VAMC purchasing staff.[22] VHA officials told us that the agency has no policies requiring VAMC purchasing staff to check whether tissue vendors are registered with the FDA when making these purchases.
- VHA likewise does not require VAMC purchasing staff and contracting officers to check FDA registration status of the tissue product vendor for open-market purchases over $3,000. Such purchases are rare—just 6 percent of VHA's fiscal year 2013 tissue product purchases were open-market purchases over $3,000.
- Finally, VHA can also purchase tissue products through national, regional, or local contracts, including national-committed use contracts and Federal Supply Schedule (FSS) contracts.[23] Of VHA's fiscal year 2013 tissue product purchases, 40 percent were FSS purchases below $3,000 and 2 percent were FSS purchases greater than $3,000.[24] VA officials stated that before issuing an FSS contract they check vendors' FDA registration status for medical devices and

[22]The Federal Acquisition Regulations (FAR) are government wide regulations that establish uniform policies and procedures used by all executive branch federal agencies for their acquisitions. Purchases above $3,000 are completed through a contracting process that involves the VAMC purchasing staff and Networking Contract Office staff.

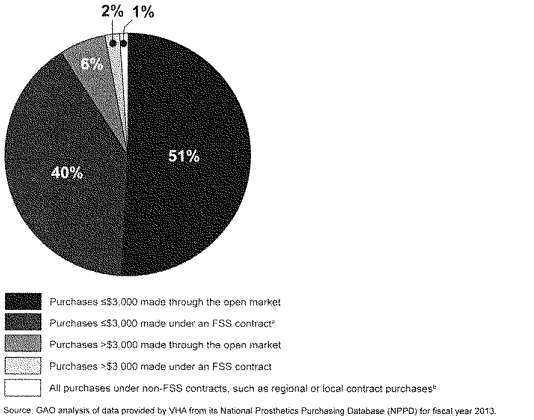
[23]These national level contracts are negotiated by VA's National Acquisitions Center. However, VHA currently has no national committed-use contracts for biologic implants, although other surgical implants could be purchased through these contracts. National committed-use contracts typically establish a fixed price for several models of a certain type of surgical implant, which VHA must use throughout its healthcare system. Federal Supply Schedule (FSS) contracts are indefinite delivery and indefinite quantity contracts awarded to vendors for various types of surgical implants and include some biologic implants, such as skin grafts.

[24]According to VA officials, there are 9 vendors with FSS contracts that could supply tissue products to VA. In January 2014, we recommended that VA develop a plan for evaluating the benefits of developing more national contracts—such as FFS contracts—with vendors of surgical implants, which could include vendors of tissue products. VA concurred with this recommendation and told us that it plans to develop a national contract procurement package for tissue products by the end of fiscal year 2014. See GAO-14-146, 26-27, 35.

drugs, which may include some tissue products. However, there is no policy requiring staff to check a vendor's FDA registration status for other tissue products, such as those regulated under FDA's human tissue regulations. Purchases under other contracts, such as regional or local contracts are rare—less than 1 percent of purchases in fiscal year 2013—and VHA has no requirements to check a vendor's FDA registration status for these purchases.

However, VHA officials stated that these data may undercount the number of purchases made under a contract, because NPPD does not require staff to enter contract information when recording purchases in the database. For VHA's tissue product purchases by purchase type see figure 1.

Figure 1: Veterans Health Administration (VHA) Tissue Product Purchases in Fiscal Year 2013



Source: GAO analysis of data provided by VHA from its National Prosthetics Purchasing Database (NPPD) for fiscal year 2013.

Note: According to VHA, these data may undercount the number of purchases made under a contract, because NPPD does not require staff to enter contract information when recording purchases in the database. This was the best data available from VHA at the time we did our work.

[a]Federal Supply Schedule (FSS) contracts are national level contracts negotiated by the Department of Veterans Affairs National Acquisitions Center.

[b]This includes all purchases under non-FSS contracts—both those above and below $3000.

VHA's Ability to Track Recalled Tissue Products May Be Limited by Poor Inventory Management Practices

In the event of a recall, NCPS informs VAMCs, which check their inventories for the recalled items; however, in the past we and VA OIG have reported concerns with VA's inventory management practices.[25] According to VHA policy, VAMCs must have a program for responding to recalls that includes identifying numbers and locations of tissue products at the VAMCs. To ensure products are removed, VAMCs are required to report the results of these inventory searches to NCPS—which manages recalls for VHA and documents recalled products found in VAMC inventories in VHA's recall database.

However, VAMC inventory searches may be limited by poor inventory management practices. For example, in May 2011, we reported that VA may lack complete information about expendable medical supplies and reusable medical equipment in its inventories.[26] In the event of a manufacturer recall or patient safety alert for such items, VAMCs may be unable to use their inventory management systems to systematically determine whether the affected items are in their facilities. Instead, they may need to resort to a physical search, which could miss items, creating the risk that recalled products could be used in patient care. This is consistent with findings of our previous work related to VAMCs' poor inventory management practices. In our 2011 report, we recommended that VAMCs be required to enter information about all expendable medical supplies and reusable medical equipment into an appropriate inventory management system.[27] To address deficiencies we identified, VHA issued new requirements in 2011 for the management of medical supplies and equipment in VAMCs inventories. However, in 2013 we

[25]NCPS learns of recalls from designated officials at the regional and local level; other federal agencies, including FDA and the Department of Defense; and tissue vendors. According to VHA Directive 2008-080, vendors are required to notify VHA of any recalls or important product safety issues. VHA is required to report to NCPS any problems identified by its subordinate chain that may necessitate a recall, such as voluntary recall notices received from tissue vendors and observed clinical problems with tissue products. VHA is also required to contact NCPS should it become aware of a recall or other product safety information from vendors.

[26]GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, GAO-11-391 (Washington, D.C.: May 3, 2011).

[27]GAO-11-391, 19.

again reported that none of the VAMCs we reviewed had fully complied with all of VHA's new requirements for managing inventories, and that VAMC inventories were still incomplete. We additionally recommended that VAMCs ensure that medical supplies and equipment are tracked in the appropriate inventory management system and VA concurred with our recommendation and described specific actions that it plans to take to improve VMACs' compliance with VHA's new requirements for managing inventories, such as providing training to VAMC staff.[28] If these recommendations are effectively implemented, it will help improve VA's overall inventory management practices.

Similarly, in March 2012, VA OIG reported concerns that VHA's prosthetics inventory data—which includes tissue products—are incomplete and inaccurate.[29] VA OIG officials reported that VAMCs should use an automated inventory system—the Prosthetics Inventory Package—to manage certain prosthetic inventories including tissue products.[30] However, VA OIG told us that the few tissue products found at the VAMCs they inspected were tracked in inventory spreadsheets or logs, rather than through the Prosthetics Inventory Package. These informal tracking systems are maintained by clinical staff in the operating room and are therefore not standardized or shared across VAMCs. They are prone to error due to manual entry, thus making accurate identification of all recalled products and oversight of VAMCs' actions more challenging. In addition, when conducting the work for this statement, VA officials told us that NCPS would not notify VAMCs of recalls in certain situations; for example, if FDA reports that the recalled product is expired at the time of reporting and thus should no longer be in VHA's inventory. However, VA OIG also found that expired products often remain on VAMC's inventory shelves, which suggests that they may retain expired products that have been recalled. VA OIG recommended that VAMCs be required to conduct comprehensive physical inventories

[28]GAO, *Veterans Health Care: VHA Has Taken Steps to Address Deficiencies in Its Logistics Program, but Significant Concerns Remain*, GAO-13-336 (Washington, D.C.: Apr. 17, 2013), 7-8, 25.

[29]The VA OIG report reviewed VHA's prosthetic inventory management practices. Department of Veterans Affairs, Office of the Inspector General, Office of Audits and Evaluations, *Veterans Health Administration: Audit of Prosthetics Supply Inventory Management*, 11-00312-127 (Washington, D.C.: Mar. 30, 2012).

[30]VA OIG 11-00312-127, 14.

of stocked prosthetics supplies and adjust the Prosthetics Inventory Package to match inventory quantities. It also recommended that the Prosthetics Inventory Package be replaced with a comprehensive modern inventory system and a mechanism be established to identify surgical device implants stored in VAMC inventories. VA concurred with these recommendations. According to VA OIG, VA completed its physical inventory in June 2012 and plans to have a comprehensive inventory system in place in March 2015. VHA's development of a mechanism to identify surgical device implants in inventories is in process.[31]

Although NCPS tracks and responds to recalls, NCPS does not track warning letters, which notify vendors of violations found during inspections, including conditions that could lead to tissue contamination.[32] VA officials stated that they do not track warning letters because they are intended to give vendors an opportunity to take voluntary corrective action before FDA initiates an enforcement action and do not necessarily provide information on specific tissue products. For example, in 2012, FDA issued a warning letter to a vendor used by VHA that outlined problematic inspection results including conditions that could result in accidental exposure of tissue products to communicable diseases. NCPS officials explained that they did not receive this FDA warning letter, and would not expect to, as there is no recall action indicated in these letters.

Identification of Recalled Tissue Products Already Implanted, Applied, or Injected May Be Limited, but VA Is Taking Steps That May Improve Its Ability to Identify Such Products

VAMCs are responsible for checking for and accurately identifying all tissue products subject to a recall that have been implanted, applied, or injected. However, VA and VHA conduct no oversight to ensure this is done. While we did not review policies and procedures that may exist at individual VAMCs, our work suggests that VAMCs' ability to check for implanted, applied, or injected tissue products may be limited. NCPS officials told us that, unlike tissue products stored in VAMCs' inventories, NCPS is not responsible for managing and documenting recalls of tissue products that have been used and does not require VAMCs to report back the results of their search for these tissue products. Rather, according to officials, each VAMC is responsible for ensuring it tracks the recalled products to individual patients. However, there is no oversight at the VA

[31]VA OIG, 11-00312-127, 21-22.

[32]FDA issues warning letters for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected.

or VHA level to make certain that VAMCs are indeed conducting this check. In addition, VHA officials stated that it is difficult to search for this information. For example, although VAMC operating room staff have been required to include the serial and model numbers of the tissue products used in the surgical patient records since 2011, VHA officials told us that there is no way to automatically search these data. Consequently, according to VHA officials, VAMCs generally rely on tissue product vendors to provide information on the medical facilities that have received recalled tissue products and staff must check individual patients' records to verify the vendor's information. Further, the quality of the data on tissue products recorded in the surgical patient records—which is entered manually by clinical staff—has not been assessed. It also does not include information on tissue products used in outpatient settings, such as skin grafts—one of VA's more commonly used tissue products. VHA's National Prosthetics Purchasing Database—NPPD—contains the serial and model number of prosthetics used for individual patients, including tissue product implants; however, VHA officials told us that NPPD is not used to track patients with implants in the case of a recall, but is generally used for purchasing and accounting purposes. Additionally, we recently reported that NPPD data was often found to be incomplete or incorrect.[33]

VA is taking steps that may enhance its ability to identify implanted, applied, or injected tissue products at VAMCs. VHA began developing a system, the Veterans Implant Tracking and Alert System (VITAS), in 2008. VITAS provides a means to track and retrieve identifying information—including the serial and lot number—of surgical implants placed in patients, including tissue products. VITAS's development was temporarily suspended due to data-reliability challenges stemming from inaccurate or missing entries in NPPD and interoperability challenges between VITAS and other VHA systems. However, VA officials told us that they plan to fund further development of VITAS in fiscal year 2014. In addition, VHA officials told us that they have established a working group to determine the feasibility of utilizing scanning and tracking technology to automatically upload tissue product implant information into electronic

[33]We reported in January 2014 that the lot number and serial number of items used in patients is not always entered into NPPD by purchasing and procurement staff, as required. In addition, this information must be entered manually, which has the potential to cause inaccuracies in information that is entered into NPPD. GAO-14-146, 33.

patient medical records.[34] Scanning a universal code on a tissue product can reduce errors in tracking implants; for example, those that occur when transcribing this information into patient records by hand. In addition, FDA issued a final rule on September 24, 2013, to establish a system to identify devices through distribution and use. The rule requires the label of medical devices to include a unique device identifier (UDI) in plain text and in a form that uses automatic identification and data capture technology, such as a bar code scanner. This rule applies to tissue products regulated under FDA's medical device regulations, and could help with the identification of these products both before and after they have been used.[35]

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this statement include Geri Redican-Bigott, Assistant Director; Emily Binek; Deirdre Brown; Sandra George; and Cathleen Hamann.

[34]Officials also cited another recent change noting that as of January 24, 2014, this tissue implant data from the medical records can be captured in VHA's Corporate Data Warehouse, which would allow these data to be extracted and searched at a national level. However, access to the data is permission-based, and while VHA officials said the data could be searched at a national level, there are currently no VHA policies in place for VHA or VAMC staff to search the database during a recall.

[35]This rule does not apply to products subject only to FDA's human tissue regulations. These requirements will be phased in over a 7-year period; however, the labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI within 2 years. 78 Fed. Reg. 58786 (Sept. 24, 2013).

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STATEMENT OF FRANK WILTON
CHIEF EXECUTIVE OFFICER
AMERICAN ASSOCIATION OF TISSUE BANKS
MCLEAN, VA

FOR PRESENTATION BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HEARING TITLED "VA & HUMAN TISSUE: IMPROVEMENTS NEEDED FOR VETERANS SAFETY"
APRIL 2, 2014

Chairman Coffman, Ranking Member Kirkpatrick, and Distinguished Members of the House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations:

Thank you for the additional opportunity to come before you today in support of the "Biological Implant Tracking and Veteran Safety Act of 2014." This critical legislation directs the Secretary of Veterans Affairs to adopt a standard identification system for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the success of the implementation of the Unique Device Identifier, or UDI, this legislation will ensure that biological implants used within the Department can be appropriately tracked from a human tissue donor all the way to the recipient. This critical capability for "track and trace" efforts will enhance patient safety, expedite product recalls when necessary, assist with inventory management, and improve efficiencies.

This legislation takes a bold step to expand the UDI to all tissue products. In addition to human tissue-devices (which are already covered by the UDI), the legislation adds another product category: certain biological implants or, as termed by the Food and Drug Administration (FDA), 361 human cells, tissues, and cellular and tissue-based products, or HCT/Ps. While many of the biological implants do have company specific bar coding information, by requiring a standardized format for those bar codes, as outlined in this legislation, it will be easier for the Department of Veterans Affairs' medical facilities to utilize universal bar coding conventions and to realize the full benefit of a unique identification system. Finally, by applying a system which has been developed for devices to biological implants, such a solution should also be applicable to other health care settings and other health care systems (such as the Department of Defense health care system or the private sector).

As the Secretary of Veterans Affairs opts to adopt the standard identification protocol for tissues (both devices and non-devices), the American Association of Tissue Banks urges you to ensure that the Secretary provide a menu of options for such adoption. Under the UDI final rule, FDA has done just that by providing for multiple entities called "issuing agencies." At this time, FDA has provided for three different issuing agencies: (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA. I hope that this flexibility is maintained within the Department of Veterans Affairs. However, given that the bill language already suggests that the unique identification system is comparable to what the UDI provides, we believe the intent to provide that flexibility is inherent in the legislation.

For those of you unfamiliar with my organization, the American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals **more than 125 accredited tissue banks and approximately 850 individual members**. These banks recover tissue from more than **30,000 donors** and

distribute in excess of **two million allografts for more than one million tissue transplants performed annually in the U.S.** The vast majority of tissue banks that process tissue maintain AATB accreditation, and the AATB estimates that only 5-10% of the allografts distributed are from tissue donors who were not determined to be suitable by the medical director of an AATB-accredited tissue bank. The AATB does not have a similar estimation for tissue distributed by tissue distribution intermediaries.

The Association was founded in 1976 by a group of doctors and scientists who had started in 1949 our nation's first tissue bank, the United States Navy Tissue Bank. Recognizing the increasing use of human tissue for transplant, these individuals saw the need for a national organization to develop standards, promote ethics and increase donations.

Since its beginning, the AATB has been dedicated to improving and saving lives by promoting the safety, quality and availability of donated human tissue. To fulfill that mission, the **AATB publishes standards and guidance documents, accredits tissue banks, and** certifies personnel. The Association also interacts with regulatory agencies and health authorities, and conducts educational meetings.

First published in 1984 and presently in its 13th edition, the AATB's *Standards for Tissue Banking* are recognized in both the United States and around the world as the **definitive guide for tissue banking.** These Standards are the only private tissue-banking standards published in the United States, and they are the most comprehensive and detailed tissue-banking standards in the world. As such, the **AATB's Standards have served as the model for federal and state regulations as well as several international directives and standards.** Currently, the statutes and/or regulations of 19 states (i.e., California, Connecticut, District of Columbia, Florida, Georgia, Idaho, Illinois, Kentucky, Maryland, Montana, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Virginia, and Wisconsin) reference AATB's Standards, institutional accreditation, or individual certification. And, these Standards are the basis of our accreditation process.

Human tissue is used in a wide variety of medical procedures in the VHA facilities, ranging from wound care management to hernia repair to orthopedic procedures. Human tissue is also used in a wide array of dental services, such as bone augmentation and gum tissue grafting procedures. In fact, according to a Government Accountability Office (GAO) report to this committee, biologics accounted for approximately $75 million in VHA acquisitions in fiscal year 2013. That same GAO report noted that one Veterans Affairs Medical Center (VAMC) had a high percentage of purchases missing serial numbers or lot numbers (16 percent in the first three quarters of fiscal year 2013).[1] I'm hopeful that this legislation will appropriately address this outstanding concern, without providing an undue burden on the health care system. For this and many other reasons, AATB supports this critical legislation.

I realize that some of you may be concerned that this legislation is duplicative and more burdensome than the FDA UDI requirements. If that were the case, it would be difficult for my organization to support its implementation. Rather, as I outlined earlier, the legislation is not duplicative of FDA's efforts because it expands the standard identification system from only devices to also cover 361 HCT/Ps. Thus, it goes beyond what Congress directed FDA to do with respect to the UDI. However, in talking to executives of the tissue banks who currently have products on the Federal Supply Schedule (FSS), all are strongly considering expanding the unique identifier to their entire product line because they acknowledge that it is an appropriate value-added benefit for hospitals and other facilities who procure tissue and, ultimately, patients, including veterans.

[1] http://www.gao.gov/assets/670/660105.pdf

As for the specific timeframes outlined in the legislation, per the UDI, tissue banks will need to develop and implement the new bar coding technology for newly produced biological implants by the end of September 2015. Assuming that this legislation is enacted this Fall and that the Secretary is able to comply with the timeframes outlined in the legislation, then the timeframes for the VHA implementation and the FDA UDI implementation would coincide. Thus, by ensuring that the standard identification system conforms to the requirements and timelines outlined by the FDA, it should not place an undue burden on tissue banks; but, there will be some costs involved.

While I do not have any specific information on the implementation cost of the UDI related to tissue banks, according to a Booz-Allen Hamilton report, the primary cost of the UDI to manufacturers relates to the need to modify or replace information technology or IT systems. For manufacturers, the cost is estimated to be anywhere between $100,000 and $100,000,000, depending on the size and scale of the changes required. Given this broad range, my expectation is that, at least for tissue banks, due to their size, it's more likely that the change will be toward the lower end of the spectrum. That being said, because there is no return on investment, it is likely that tissue banks will need to increase the fee for tissue products to cover the cost of those changes.

But, such an increased cost to the VHA is worth the end result of enhancing patient safety. As the VHA has acknowledged with the previous efforts to create the Veterans Implant Tracking and Alert System or VITAS, there are current gaps in the information collection process for biological implants. As you know, VITAS was designed to track and retrieve identifying information—including the lot and serial number—of surgical implants placed in patients VHA-wide. Therefore, VITAS was developed to address shortcomings in VHA's existing ability to "track and trace" surgical implants. And, without additional developments, VHA's ability to identify and locate patients who received an implant in the event of a manufacturer or FDA recall may be limited. Unfortunately, as outlined in a recent GAO report, due to data-reliability and interoperability challenges, VITAS was suspended at the end of fiscal year 2012. And, as of December 2013, VHA had not decided whether to resume the development of VITAS.

While I can understand your skepticism in requesting the VHA attempt a VITAS-like enterprise in this legislation after failing to do so before, I would note that a lot has changed since 2008 when the VHA first envisioned VITAS. First, there is now a UDI benchmark which allows those developing the necessary software for data capture to move from a design incorporating dozens of different bar coding technologies from all of the AATB-accredited tissue banks to only three different ones outlined by the three different issuing agencies. Thus, the task is much easier. In addition, the VHA is not alone in trying to develop a system for integrating the UDI-like information directly into the medical record. For instance, the Office of the National Coordinator for Health Information Technology (ONC), which is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information, is currently focused on ways in which the UDI can be better operationalized to ensure its adoption into HL7 standards – the key standards for the exchange, integration, sharing, and retrieval of electronic health information. As part of those efforts, ONC is initially focusing on implantables – the very focus of the legislation we are discussing today, suggesting that this is an area of potential "low hanging fruit" in which a small investment can reap a big reward. Therefore, the VHA will not be attempting to establish such a system alone but can partner with other governmental entities to ensure its success.

Finally, when I last discussed this legislation before the Committee, I noted my concern that the draft legislation lacked a requirement that biological implants purchased by the VHA be subject to

appropriate accreditation standards. It's my understanding that those concerns are addressed in the latest version of the legislation by requiring accreditation by AATB or a similar accreditation organization. Thus, with this change, the VHA will be joining the ranks of leading medical centers of excellence which currently require all tissue to be sourced from AATB accredited tissue banks. AATB strongly supports this legislation and urges the committee to favorably report it out of committee.

I welcome your questions.

I yield back my time.

Questions for the Record
House Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
Oversight Hearing
"VA and Human Tissue: Improvements Needed for Veterans Safety"

April 2, 2014

Questions for the Record from Subcommittee Chairman Mike Coffman

Question 1: According to GAO, VA plans to fund further development of the Veterans Implant Tracking and Alert System (VITAS) in FY2014. Why then did VA not specifically ask for funding in its budget for FY 2014, FY 2015, or its advanced appropriations from FY 2016?

VA Response: VA determines which information technology (IT) projects will receive funding using a process where administrations and staff offices prioritize IT needs. During this prioritization process for Fiscal Year (FY) 2014 and FY 2015, the Veterans Implant Tracking and Alert System (VITAS) was prioritized below other funding requests, which prevented it from receiving funding through the initial budget process. However, VA allocates funding to unfunded projects as funds become available throughout the fiscal year.

Because the effort to build VITAS is an IT development project, it would be funded out of the Office of Information and Technology account, and it would not have been part of VA's FY 2016 advanced appropriations for the medical care account.

Question 2: What further development does VA have planned to utilize VITAS, and what funding will be requested to implement it, aside from the initial $750,000 requested in the 2013 budget?

VA Response: Should additional enhancements be required, VA will again consider VITAS funding with other competing priorities.

Question 3: According to GAO's testimony, VAMCs rely on product vendors to provide information on what facilities have received recalled biologics. Why does VHA not make an independent assessment?

VA Response: In nearly all cases of a recalled biologic product, the vendor for the product initiates the recall as a voluntary action with the knowledge of the Food and Drug Administration (FDA). When a vendor initiates a voluntary recall, they are required to complete a recall form and report to FDA if the product was sold to a Government agency, including VA. Therefore, the vendor of a biologic is the primary and early source for data linking a recall to a VA facility that potentially purchased a specific recalled product.

The vendor initiates a voluntary recall action by directing a letter to their affected customers, including affected VA facilities, to notify them of a recall. The vendor provides instructions on how to remove the product from use, issues a refund or replacement of the product, and requests acknowledgement of removal from inventory stock by the facility.

The Veterans Health Administration centralized the management of the recall process for all VA facilities in 2008 through the creation of the Product Recall Office (PRO), located within the VA National Center for Patient Safety (NCPS). The PRO posts recall notices with follow-up actions required by VA facilities for products known or likely to be available throughout VA's 150 medical centers and affiliates to remove the product from use. The PRO requires acknowledgement of actions taken and monitors compliance and completion of all follow-up actions related to the recall.

The PRO also independently assesses all recalls that potentially affect VA facilities. This is done through direct contact with the vendor and review of early notification of the recall provided by the Defense Logistics Agency or FDA. The PRO also reviews any information available about a recall from the FDA, vendor, or the facility. This independent review is completed by the PRO for VHA to determine if VA facilities are affected by a recall, and if so, how many and which ones require follow-up action.

If the PRO is able to determine which VA facilities are potentially affected, a recall notice is posted to target these facilities for required actions. If the PRO is unable to adequately determine impact and scope to VA, the PRO posts a recall to all VA facilities for required actions. If the impact of a recall requires clinical review, the PRO triages this for clinical investigation by subject matter experts. There are also instances in which the PRO assesses the recall and takes actions beyond those recommended by the manufacturer or FDA.

Question 4: According to GAO, VA does not conduct any oversight of whether VAMCs are checking for implanted tissue that has been recalled. How does VA plan to address this problem?

VA Response: VA is developing a national implant registry to provide a searchable database that links acquisition item details for a biologic to the patient's clinical record, ensuring traceability to the source of the biologic or biologic implant. The national implant registry will provide VHA with a standardized process to effectively track and manage recalled biologic implants across all VA facilities.

While the registry will standardize and potentially expedite the process of identifying patients, the process used to determine what clinical actions are needed will remain similar to the current process. Subject matter experts will be engaged to determine what clinical care is required for potentially-affected patients with an implant. If needed, a patient safety alert or advisory will be issued, and all alerts and advisories will be tracked according to the current process to ensure the facility closes out the required actions.

Question 5: If a biological implant, such as a skin graft, is recalled how does VA know that VAMCs have checked if this product has been used either in the surgery or outpatient setting?

VA Response: The data to track a recalled biologic implant to a patient currently exist and are available to VA facilities today, although not in an easily accessible format. The national implant registry will contain historical records, as well as new records to ensure VA facilities have a standardized method to check if a recalled product has been used in the care of a patient at VA.

Question 6: What is the time frame VA has established to address the concerns regarding the accurate accounting for and identification of all biologics in VAMC inventories to ensure no contaminated, expired, or recalled items remain? Also, please explain what steps will be taken at each point throughout that time.

VA Response: Patient safety recalls are all acted upon promptly when a patient safety alert is triggered. Each VA medical center is required to review its inventory to determine if any of the recalled items are stocked, and, if so, those items are subsequently pulled from inventory. Timelines for facility actions and reporting milestones are set for the specific recall action. VA has identified 13 product recalls in biologics and human tissue and 3 of these items were identified in VA inventories. The attached table provides details

Question 7: When does VA plan to have the results of its workgroup examining the feasibility of using scanning and tracking technology to automatically upload tissue product information into electronic medical records? Also, when the results are compiled, please provide a digital copy to the Subcommittee.

VA Response: VHA plans to have the results of its workgroup to review in the third quarter of FY 2014. Once results are reviewed and finalized, VA will share them with the Subcommittee.

Question 8: In his testimony, Mr. Matkovsky stated that twenty-two waivers were issued to purchase biologics on the open market in 2013. Please provide the Subcommittee with a digital copy of each of those waivers.

VA Response: Examples of Federal Supply Schedule (FSS) waiver documents are attached. These are images of manual copies. Also, a table listing tracked waivers from FY 2012 and

FY 2013 is attached, which identifies more than 21 waivers that include other product categories.

Question 9: In his testimony, Mr. Matkovsky stated that a waiver is not obtained every time an implant is purchased on the open market. However, according to his May 23, 2012, memorandum, "an Open Market Waiver Request must be submitted through the Chief of Procurement and Logistics Officer to the National Acquisition Center for approval." This memorandum makes submitting a request for a waiver a requirement, so why is a waiver not submitted for every such purchase?

VA Response: VA requires waivers be submitted for purchases that do not utilize national or FSS contracts. Prior to September 30, 2013, these purchases were made by staff members who were not warranted contracting officers. The process for identifying FSS schedule holders is not a simple, straightforward task and involves frontline staff to navigate a complex Web site to perform individual, manual product searches across multiple sets of files. As the purchase authority for items above $3,000 has now transitioned to procurement, quality and consistency reviews will focus on VA's compliance with waiver processes.

Question 10: In his testimony, Mr. Matkovsky stated that a simple verification of whether biological implant vendors were registered with the FDA was important for patient safety. Why then does VA not conduct this simple verification?

VA Response: VA established an Integrated Product Team to develop requirements for a national contract for biological implants and tissue products. VA agrees FDA registration should be part of procurement activities. Please note that regional and/or local contracts are typically either entered into with firms that are certified by the American Association of Tissue Banks (AATB) and/or in possession of an FSS or other Governmentwide contract vehicle. There are certain challenges to using prosthetics purchasing data, which is a reporting database, to draw definitive conclusions about sourcing practices because reporting databases do not always accurately reflect information as to which firms are in possession of a Governmentwide contract vehicle.

For example, the attached table provides a comparison of the top 10 overall biologics firms VHA purchased biological implants from in FY 2012 and FY 2013. In FY 2013, there are data anomalies, but these anomalies point out some of the challenges relative to the conclusions regarding sourcing practices when using only the prosthetics database. The prosthetics database is not a procurement system. Therefore, data entry for a VA contract number is not a mandatory field and is not reliably provided even when the item acquired is on a VA contract. In FY 2013, the following firms and overall

purchase amounts showed up on the top 10 list of firms VA purchased biologics through a Federal contract, although the table does not reflect that these firms have FSS contracts:

796560394 - AVKARE INC	$7,184,067.00
006261481 - MEDTRONIC INC	$1,184,996.00
782796705 - ADVANCED BIOHEALING INC/SHIRE	$1,140,092.00

Taken together, these firms account for over $9.5 million of biological implant purchases that were classified as "open market" - that is, a firm that does not have a Federal contract - however, each of these firms does in fact have an FSS contract. VA provides this example to demonstrate that National Prosthetics Patient Database data are not a reliable source by which to determine findings in connection with a procurement spending audit..

The Committee previously expressed concern regarding the 8 percent of firms that did not have AATB certification (Note: AATB stated that it certifies roughly 92 percent of the market). The concern stated by the Committee is related to whether or not VA increased the likelihood of purchasing biologics from firms that were not AATB certified when it did not purchase off FSS contracts. In reviewing contract histories, VA has identified that open market orders that were not committed to FSS contracts were committed to AATB-certified vendors. It should be noted that firms with FSS contracts are not necessarily AATB-certified vendors. This pattern underscores the need to implement a national contract that contains quality, clinical requirements.

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